Tethers and Growth Modulation: Update 2010

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Disclosures: DePuy Spine: Research, Consultancy, Royalties; Axial: Research; OREF: Research; Nuvasive: Stock

Rady Children's Hospital

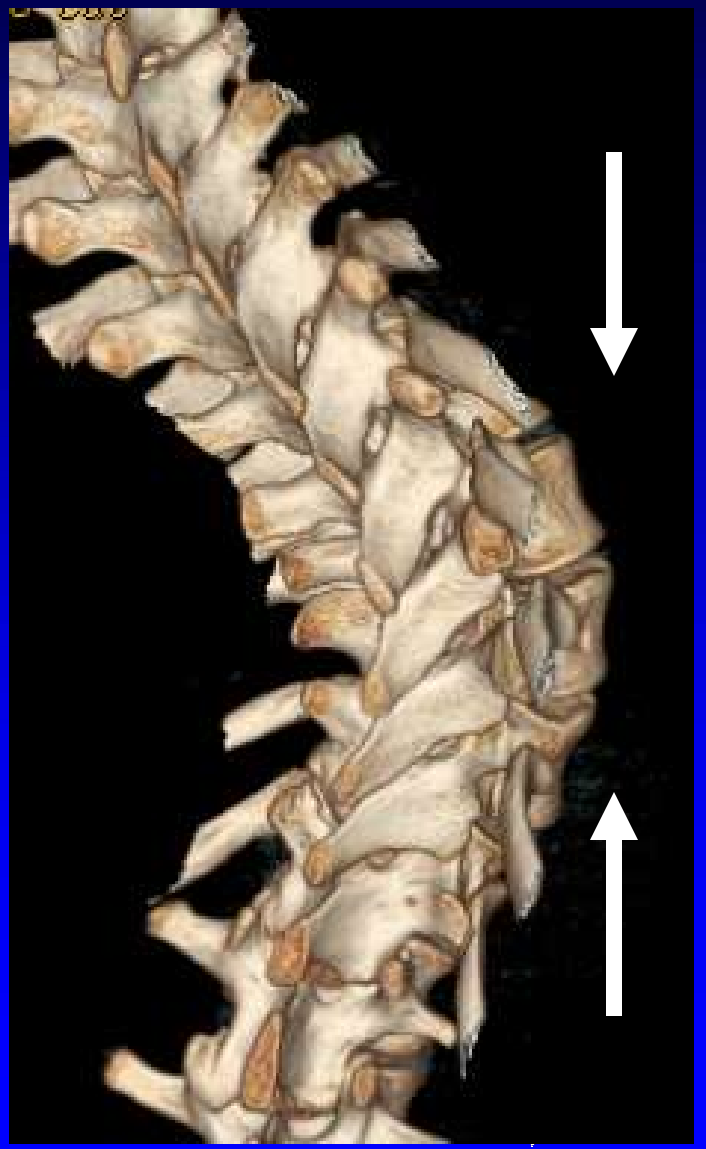
San Diego – Orthopaedics

Holy Grail of Spinal Deformity Correction

- **Correct Scoliosis without Fusion**
- **Preserve Spinal Motion / Function**
- **Use the patient's growth potential to "power" the correction**

"Relative Anterior Overgrowth"

- Too much anterior spine, rotates out of plane to "shorten" the anterior column
- Thoracic curves
- Primary driver of all 3 planes of deformity



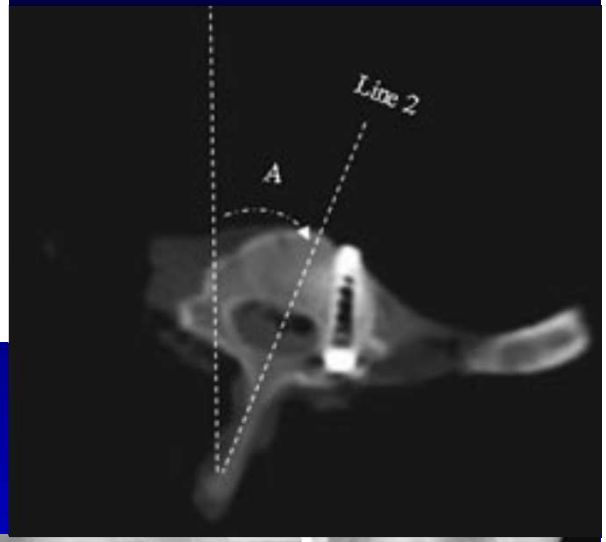
Strategies

- Slow anterior growth, especially on convex side
- Increase posterior growth, concave side
- Neurocentral synchondrosis manipulation

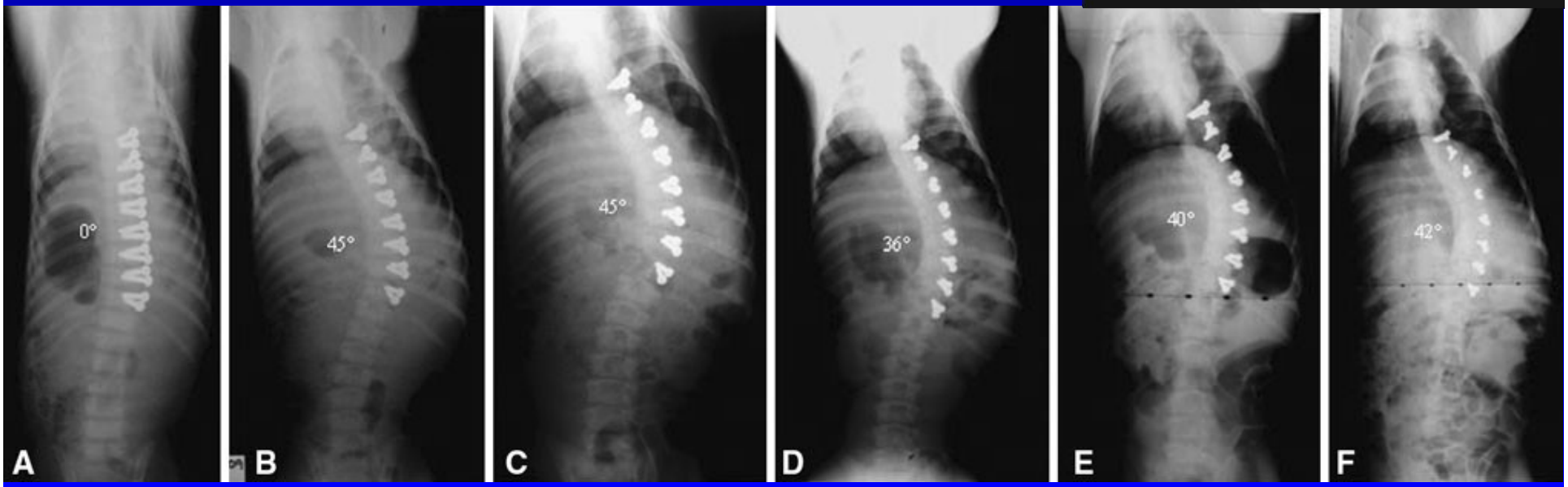
Neurocentral Synchondrosis Screws to Create and Correct Experimental Deformity: A Pilot Study

Hong Zhang MD, Daniel J. Sucato MD, MS

CORR, 2010

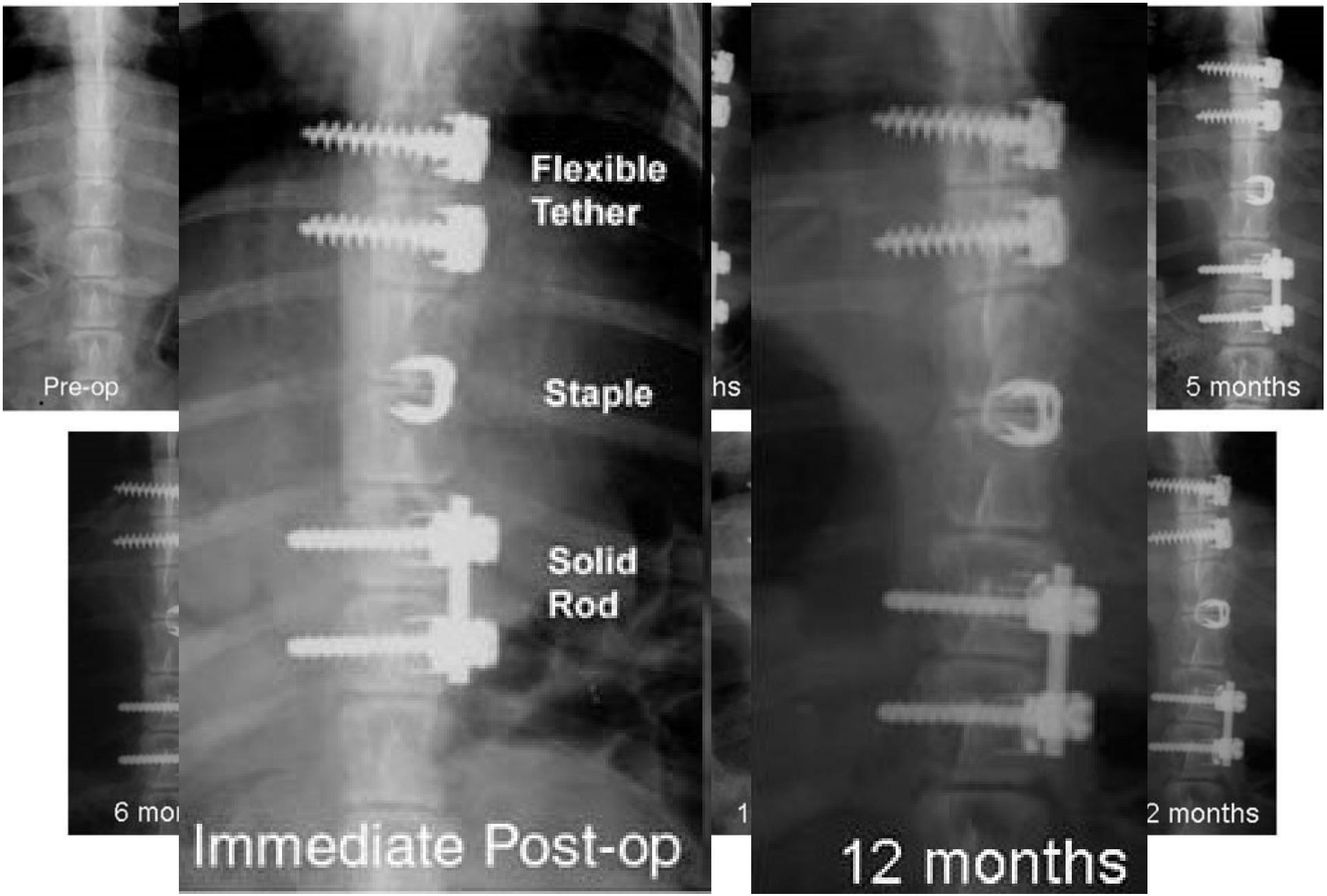


- **1 month old pig model**



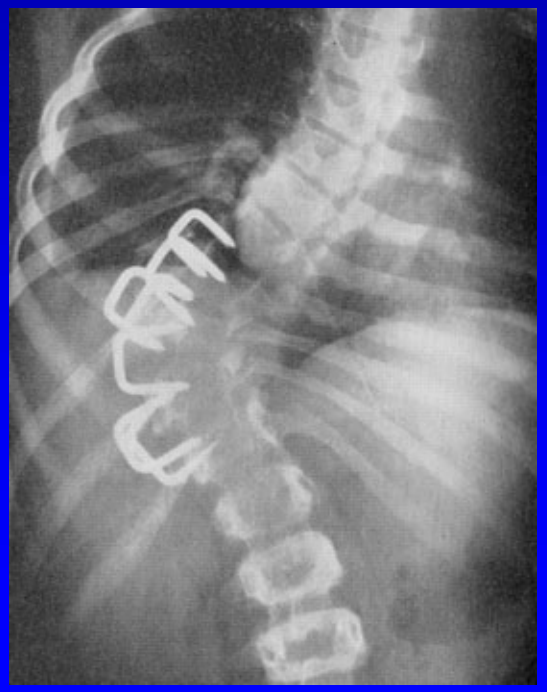
Initial 2 wks 4 wks 6 wks 10 wks 17 wks

MiniPig Comparison of: Tether, Staple, Rod

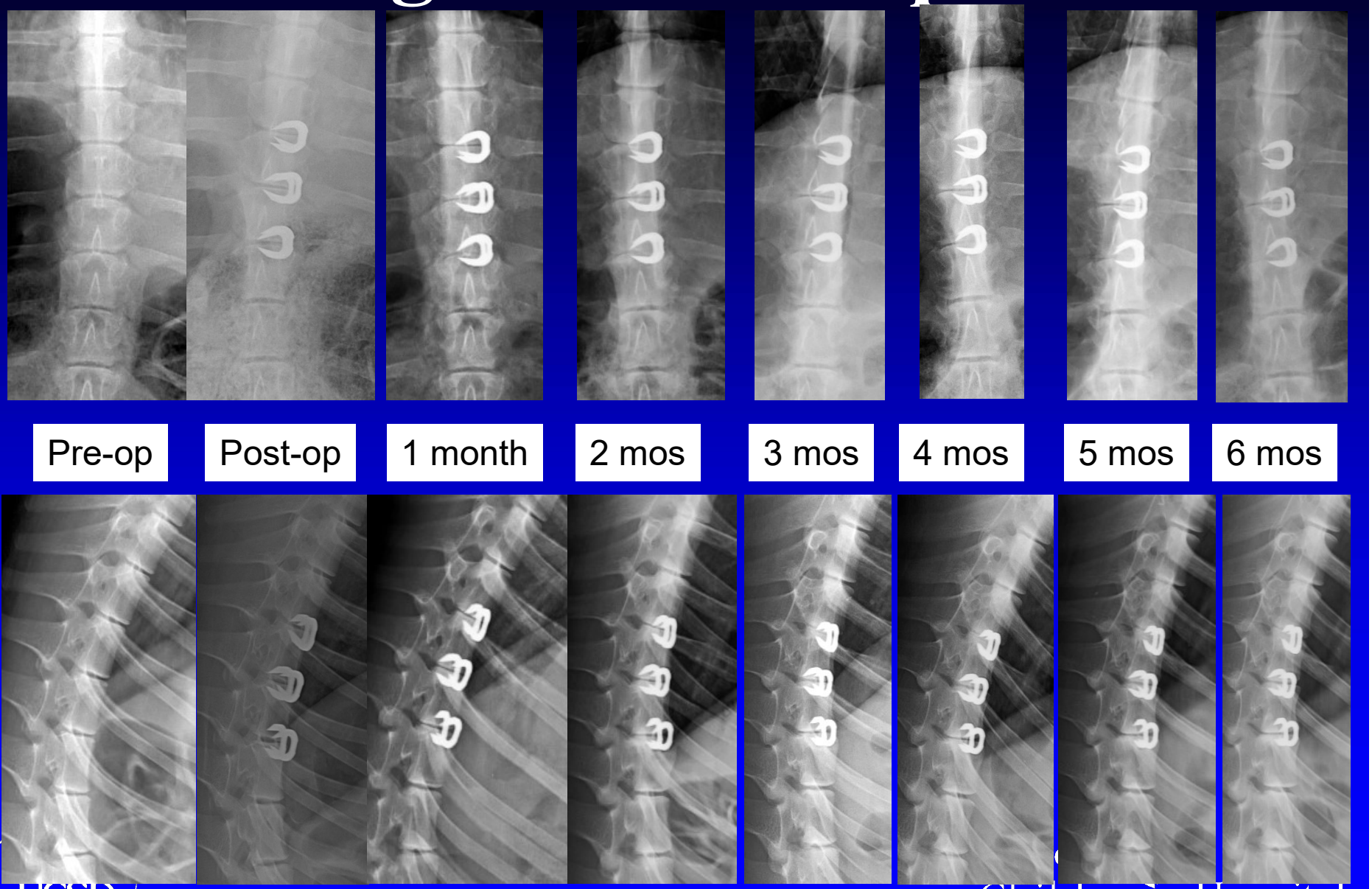


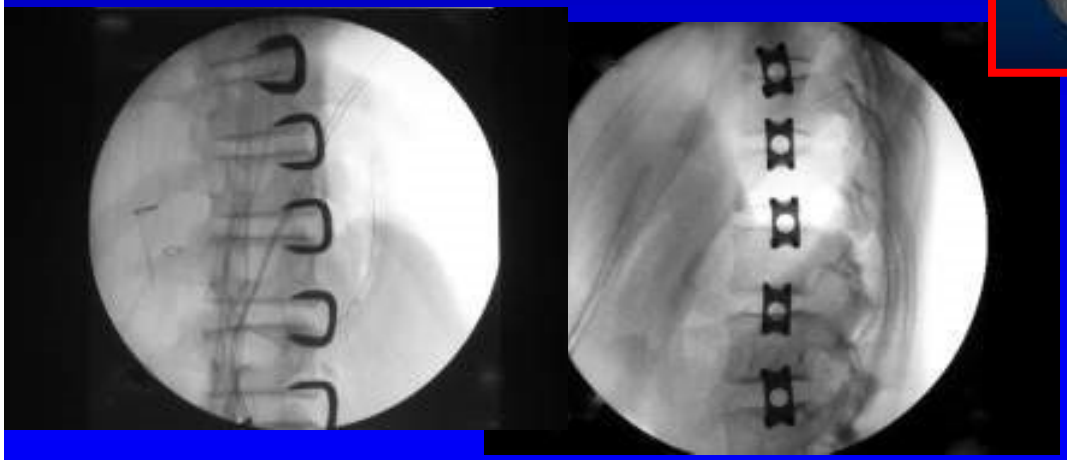
Vertebral Staples

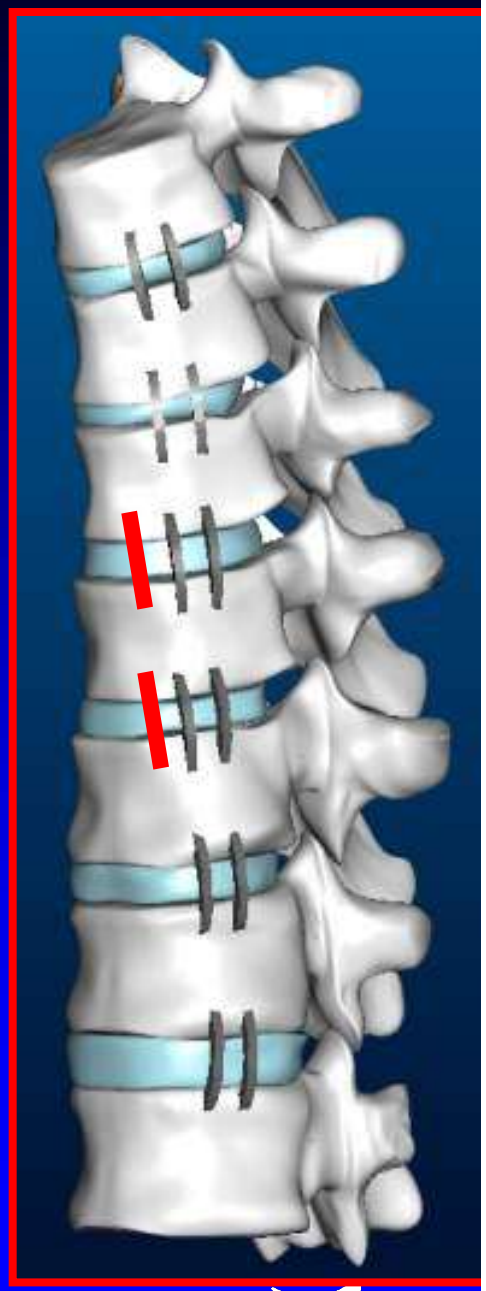
- Traditionally used for long bone correction
- Historical results in spine disappointing
- Advances in staple design
- Nitinol – Alloy with shape memory properties

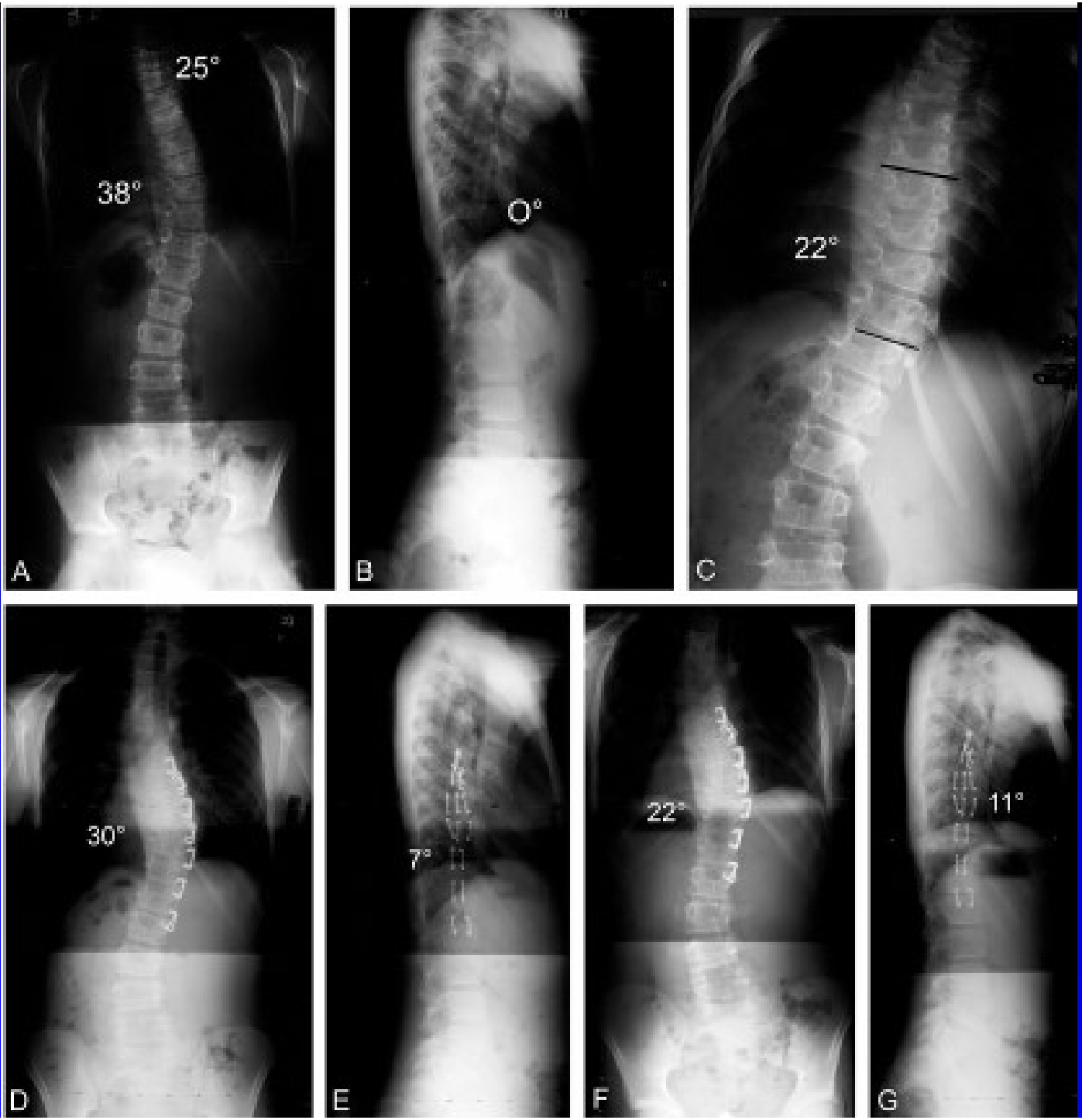


Pig: Nitinol staples









Betz et al.,
Spine 2003

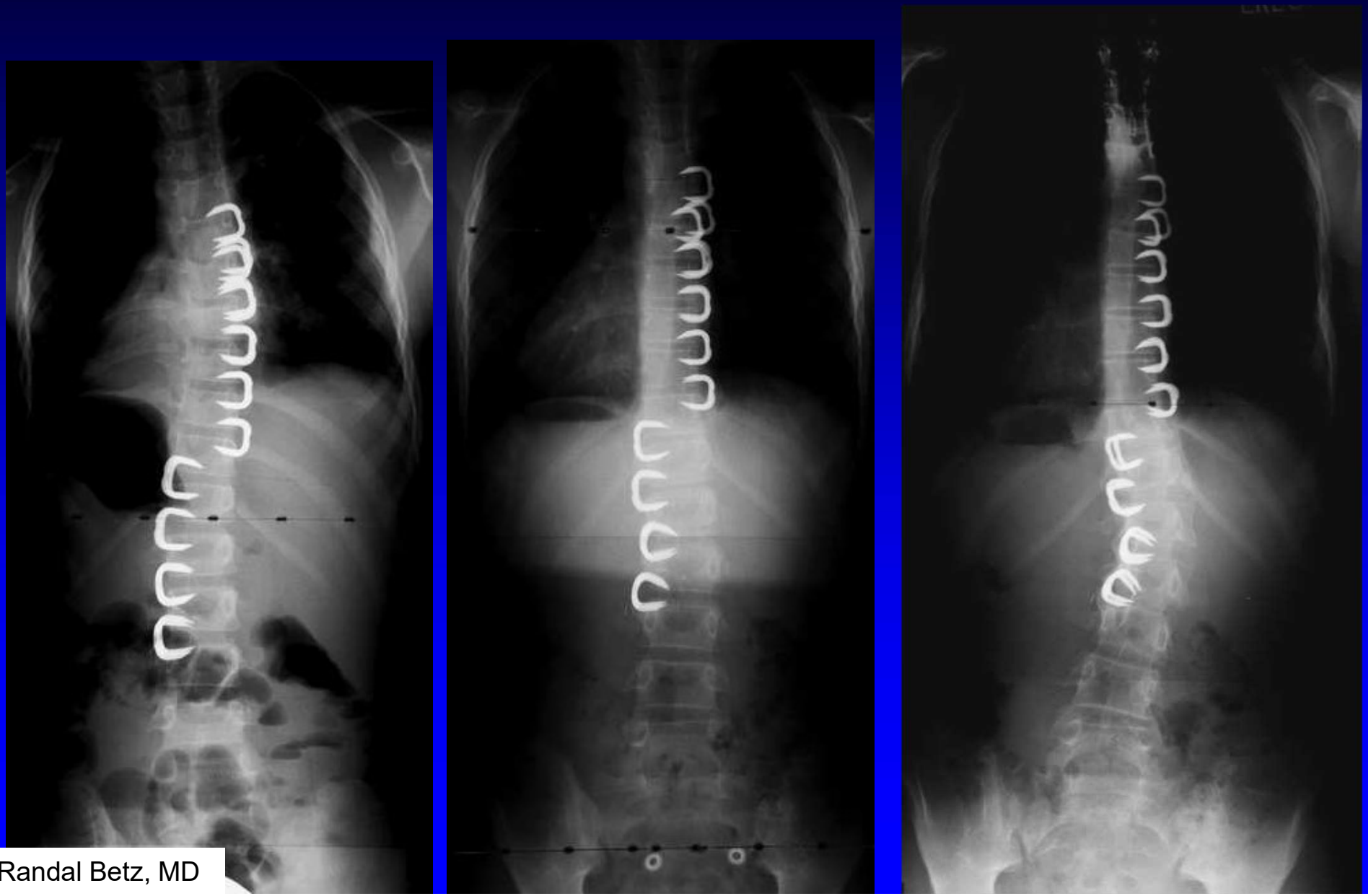
Betz, et al Data

- JIS or AIS
- Risser 0-1
- Curves 20-45 degrees
- Min 2 year follow up
- 28 of 29 patients

Stapling Results (2 yr FU)

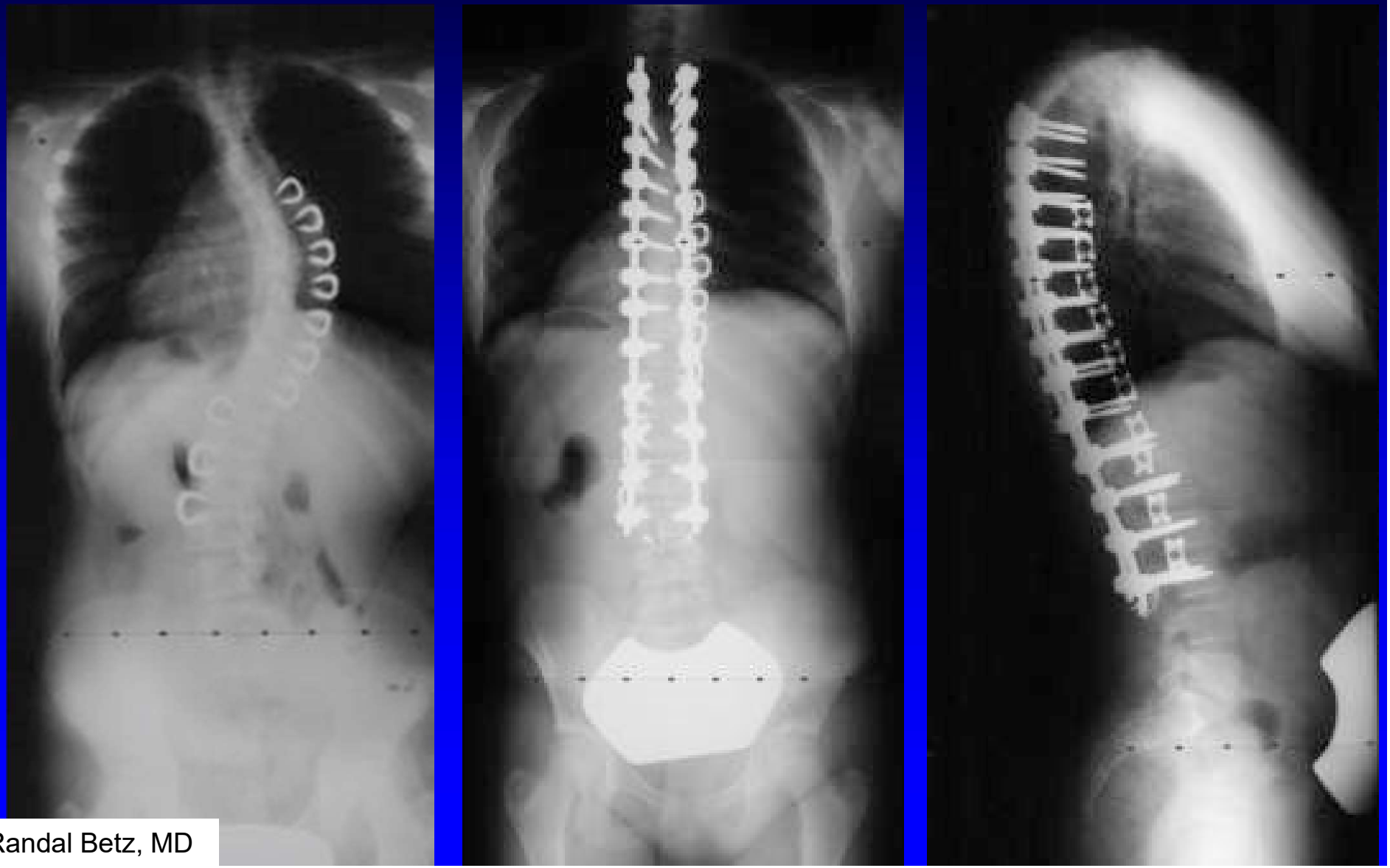
	Improved > 10	No Change	Progressed >10
Thoracic Curves < 35	17 % N=3	61 % N=11	22 % N=4
Thoracic Curves > 35	12 % N=1	12 % N=1	75% N=4
Lumbar Curves	20 % N=3	67% N=10	13% N=2

Over Correction

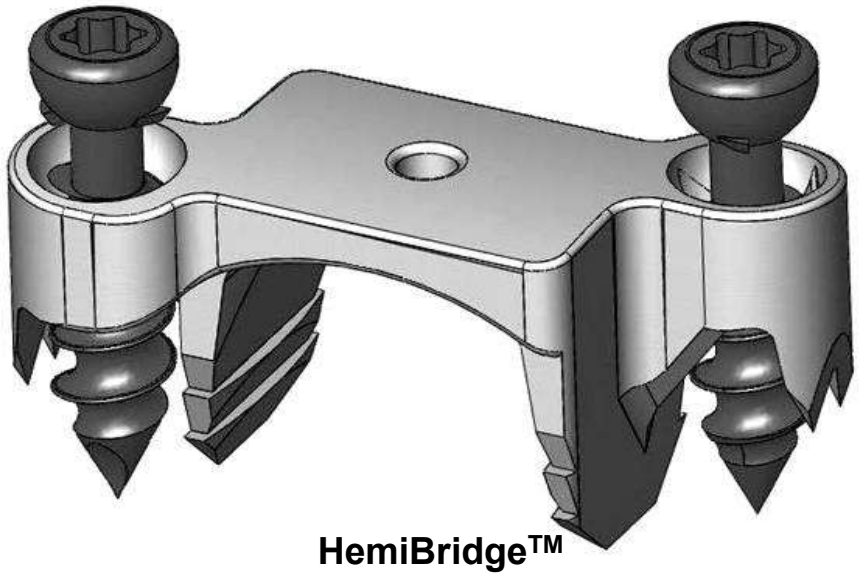


Randal Betz, MD

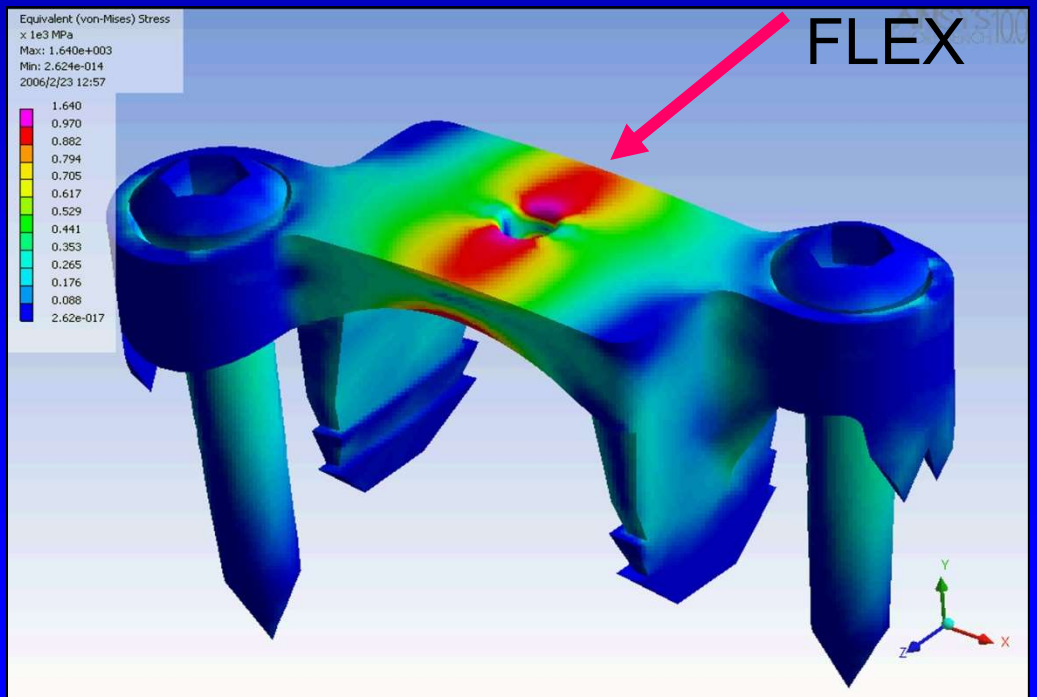
Spine Remains Flexible



Randal Betz, MD



HemiBridge™



Eric Wall, MD
Donita Austrow PhD

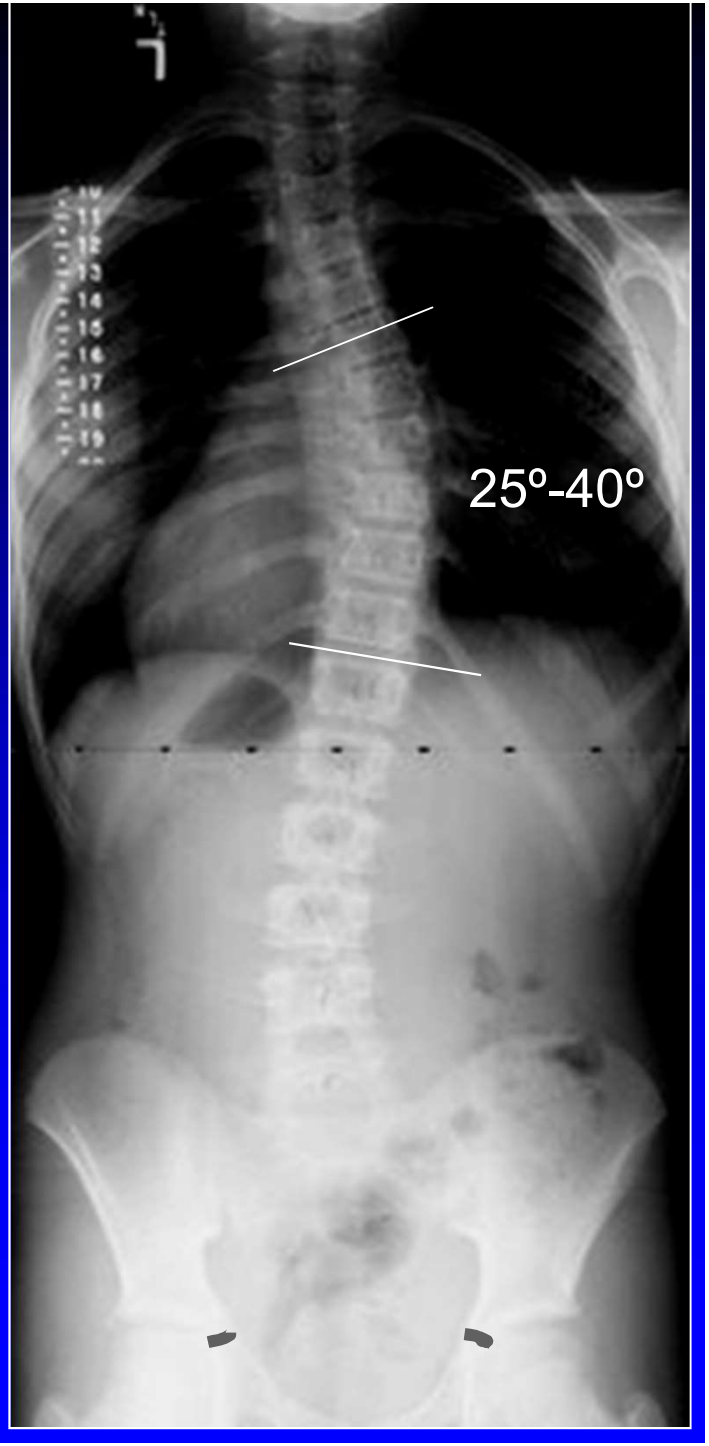
Pig Model

Eric Wall, MD
Donita Austrow PhD

FDA Approved IDE:

- **Lenke 1A, 1B Thoracic**
- **T3-L1**
- **Ages 10-15**
- **Risser 0, Open Triradiate**
- **Cobb 25º-40º**
- **Bone Age <13 girls, <15 boys**

High Likelihood for Fusion

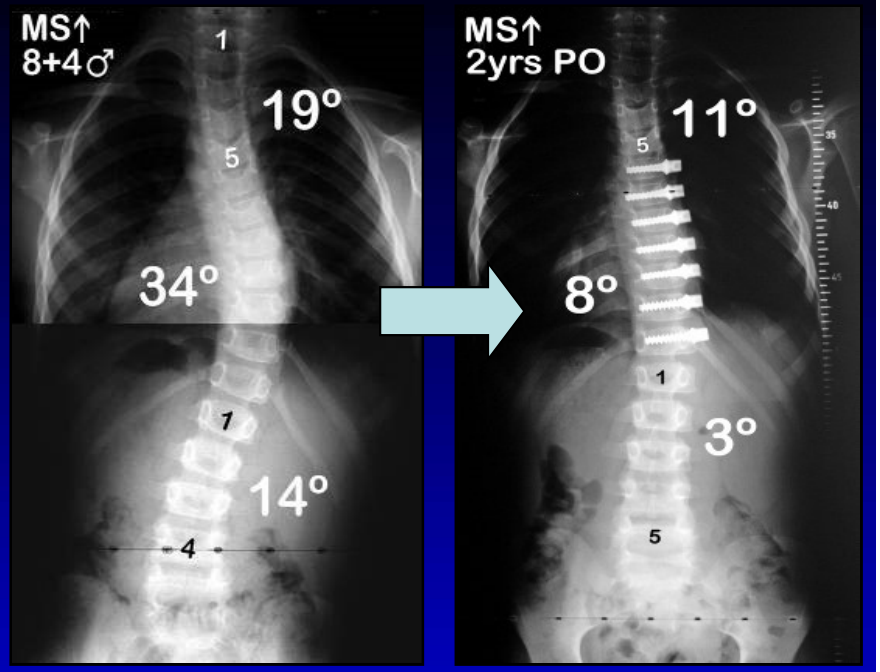


Eric Wall, MD
Donita Austrow PhD

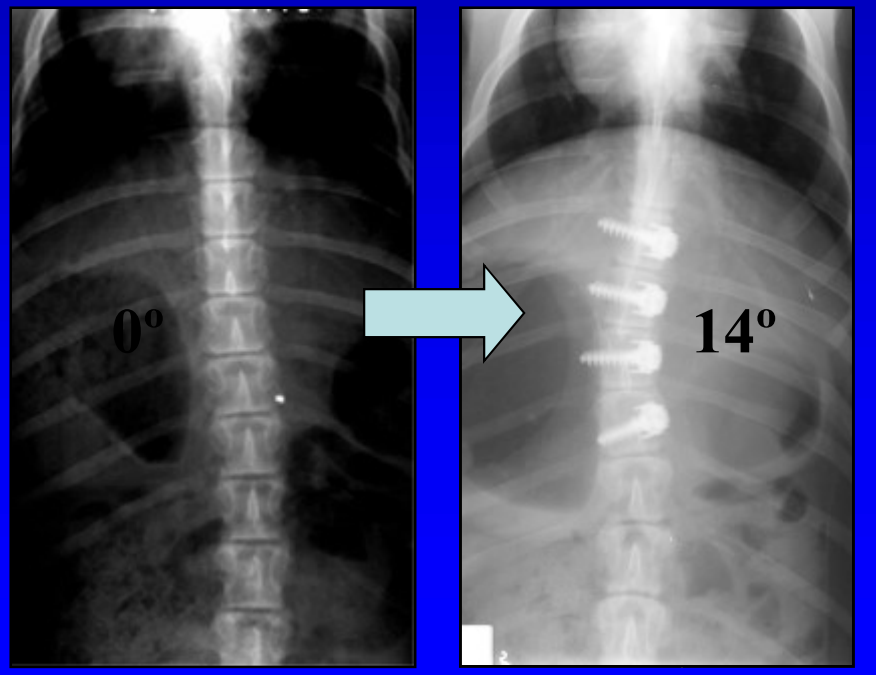
Flexible Implant?

- Tether
- Limit growth
- Allow motion except bending away from tether
- Preserve disc function/health

Clinical Application

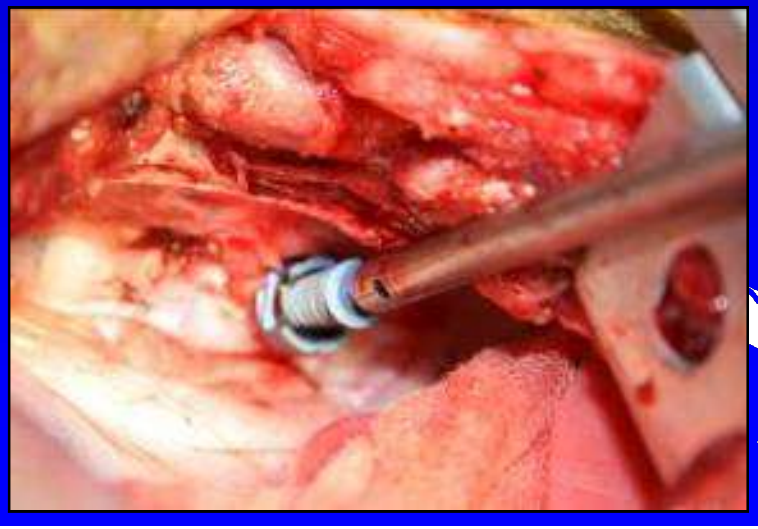


Experimental Application



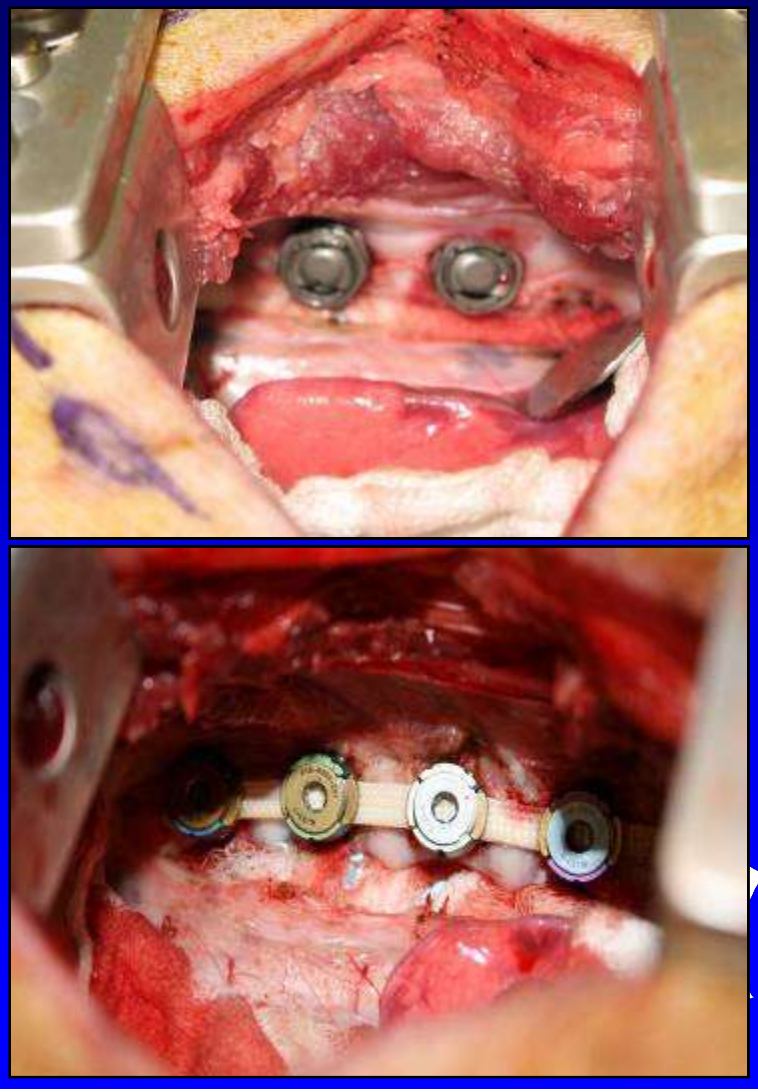
Latest Porcine Study

- Twelve 7-month-old Yucatan mini-pigs
- Right sided double thoracotomy
- T8-T11 instrumented

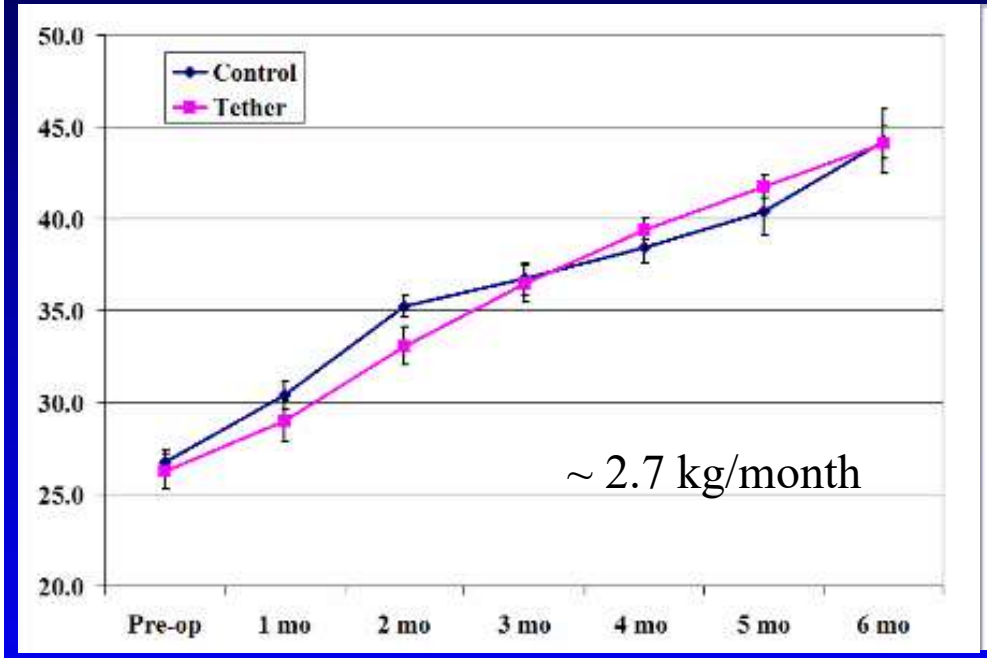


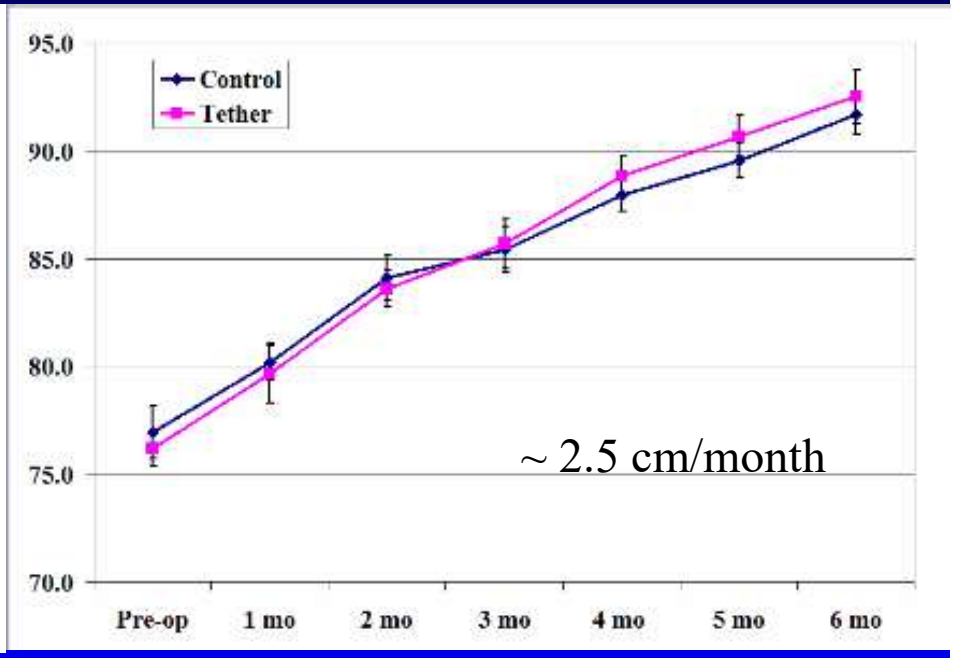
Control vs. Tether Groups

- **Control group (n=6):**
  - Sham surgery with only screws
- **Tether group (n=6):**
  - Tapered screw-staple design with a UHMWPE ribbon
- **6-month survival**



Porcine Growth

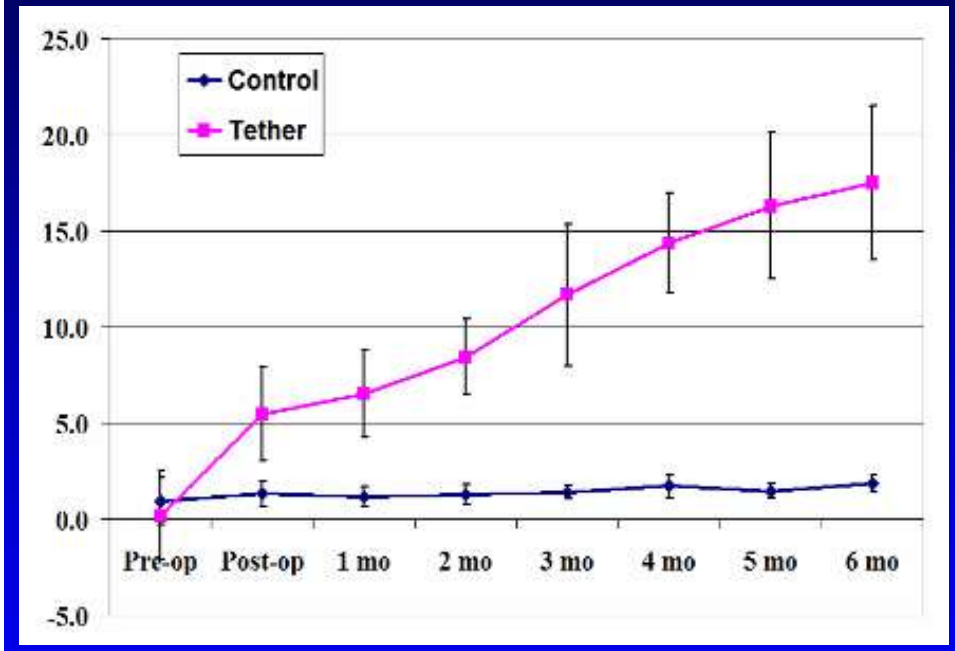


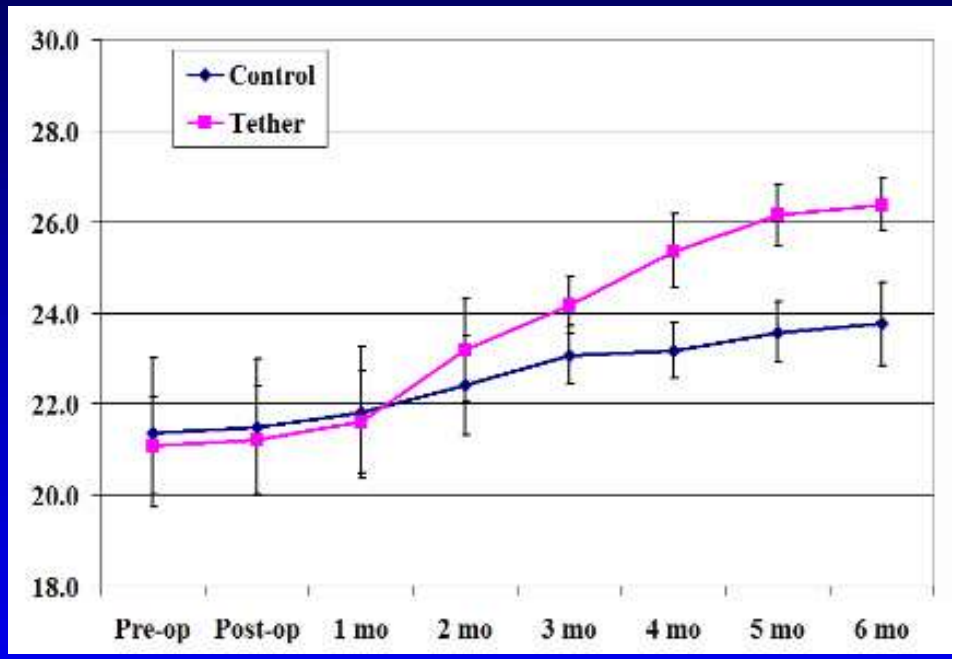


Weight (kg) **Length (cm)**

No significant differences in growth rate between the control and tether groups (p>0.73)

Deformity Creation





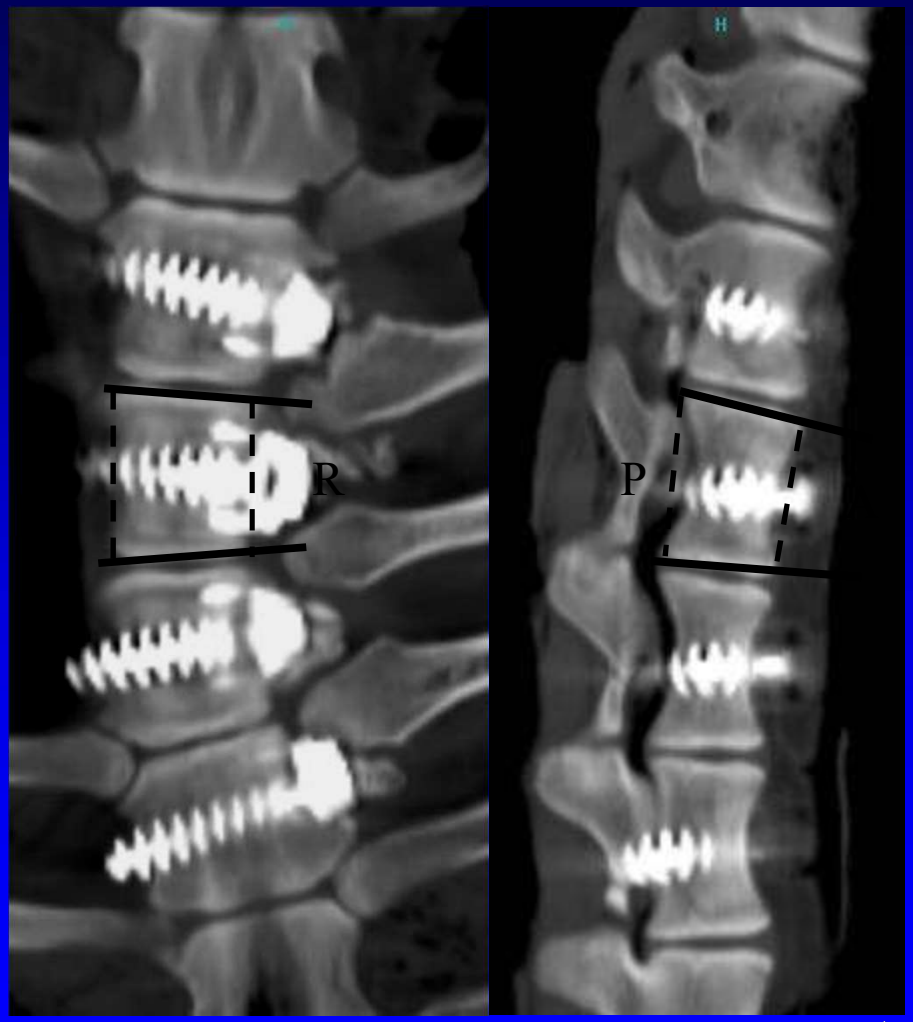
Coronal Cobb

Sagittal Cobb

Significant increase in the Coronal Cobb ($p<0.001$) and the Sagittal Cobb ($p<0.01$)

Computed Tomography

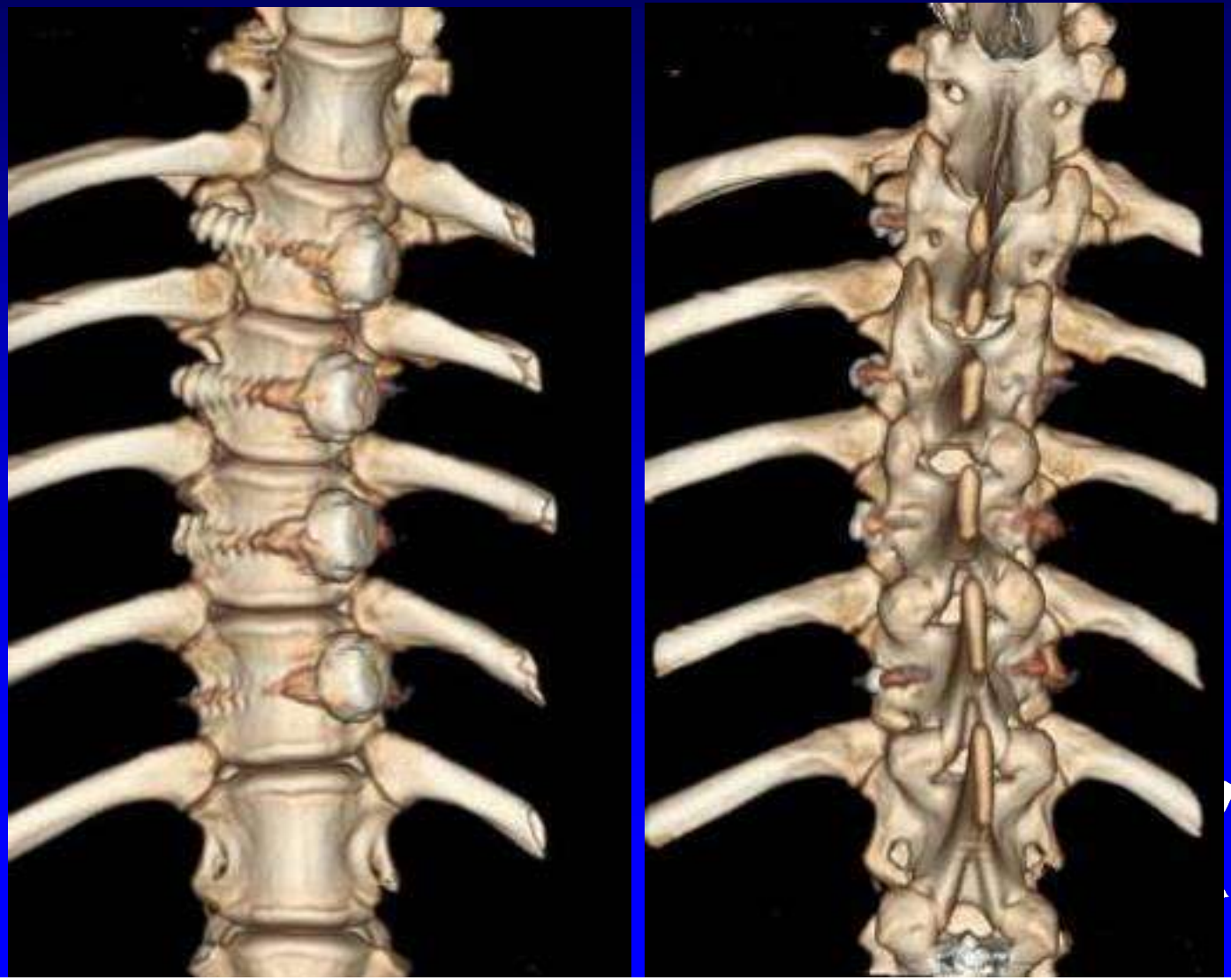
Control – 6 month post-op



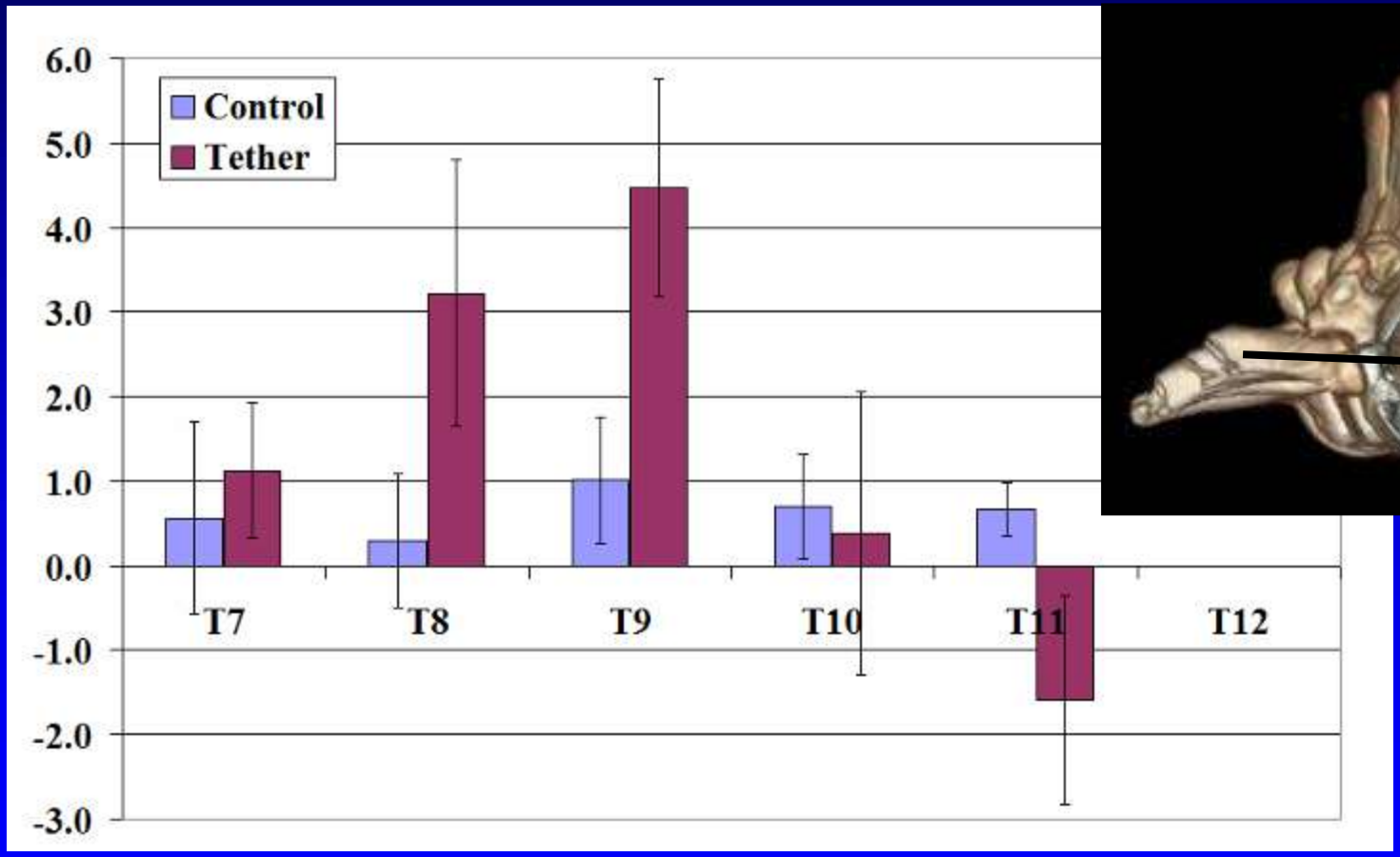
Tether – 6 month post-op

3D CT Reconstruction

Tether – 6 month post-op



Axial Plane Deformity



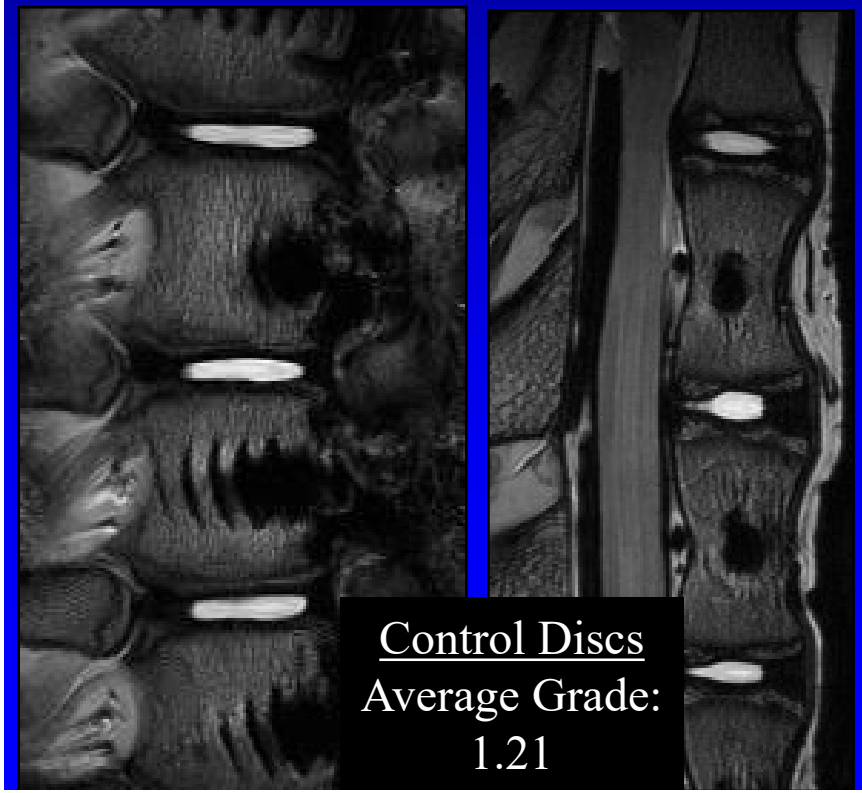
Vertebral Body Rotation

3T Magnetic Resonance Imaging

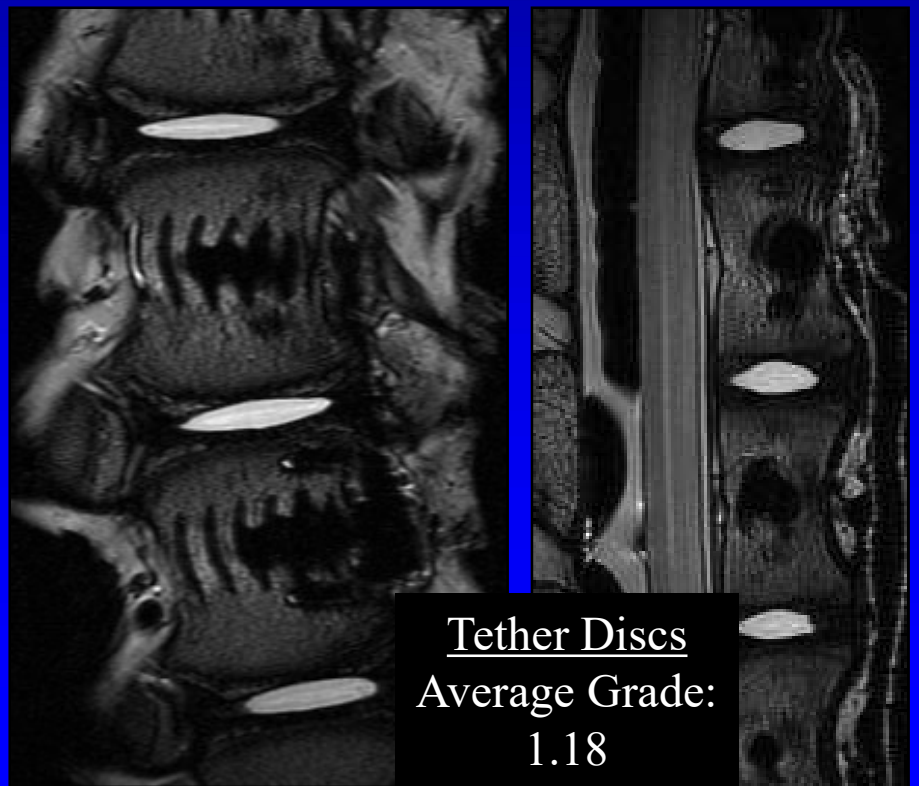
Classification of Disc Degeneration*

Grade	Structure	Distinction of Nucleus and Anulus	Signal Intensity	Height of Intervertebral Disc
I	Homogeneous, bright white	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
II	Inhomogeneous with or without horizontal bands	Clear	Hyperintense, isointense to cerebrospinal fluid	Normal
III	Inhomogeneous, gray	Unclear	Intermediate	Normal to slightly decreased
IV	Inhomogeneous, gray to black	Lost	Intermediate to hypointense	Normal to moderately decreased
V	Inhomogeneous, black	Lost	Hypointense	Collapsed disc space

* Modified from Pearce (cited by Eyre et al[9]).



Control Discs
Average Grade:
1.21



Tether Discs
Average Grade:
1.18

Gross Morphology

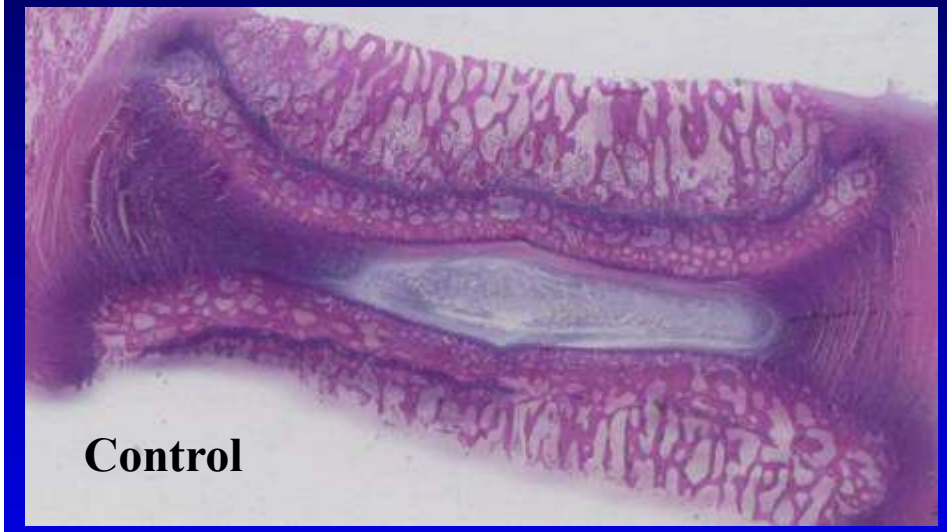
The Thompson grading scheme [42] for gross morphology of the human lumbar intervertebral disc

Grade	Nucleus	Annulus	Endplate	Vertebral body
I	Bulging gel	Discrete fibrous lamellas	Hyaline, uniformly thick	Margins rounded
II	White fibrous tissue peripherally	Mucinous material between lamellas	Thickness irregular	Margins pointed
III	Consolidated fibrous tissue	Extensive mucinous infiltration; loss of annular-nuclear demarcation	Focal defects in cartilage	Early chondrophytes or osteophytes at margins
IV	Horizontal clefts parallel to endplate	Focal disruptions	Fibro cartilage extending from subchondral bone, irregularity and focal sclerosis in subchondral bone	Osteophytes less than 2 mm
V	Clefts extend through nucleus and annulus	–	Diffuse sclerosis	Osteophytes greater than 2 mm

Control Discs
Average Grade:
1.46

Tether Discs
Average Grade:
1.35

Histological Analysis



Definition of Histological Grading Scale

I. Anulus fibrosus
Grade:
1. Normal, patt… …haped in the posterior … …r aspect) without rupture… … anywhere withi…
2. Ru… … % of the a…
3. … … of the

II. B…
Grad…
1.
2.
3.

III. …
Grad…
1. … …ucture …
2. Sl… … …es
3. Mo… … …ls and no vacu…

IV. Matrix o…
Grade:
1. Normal gela…
2. Slight condensat… …atrix
3. Moderate/severe condens… … the extracellular matrix

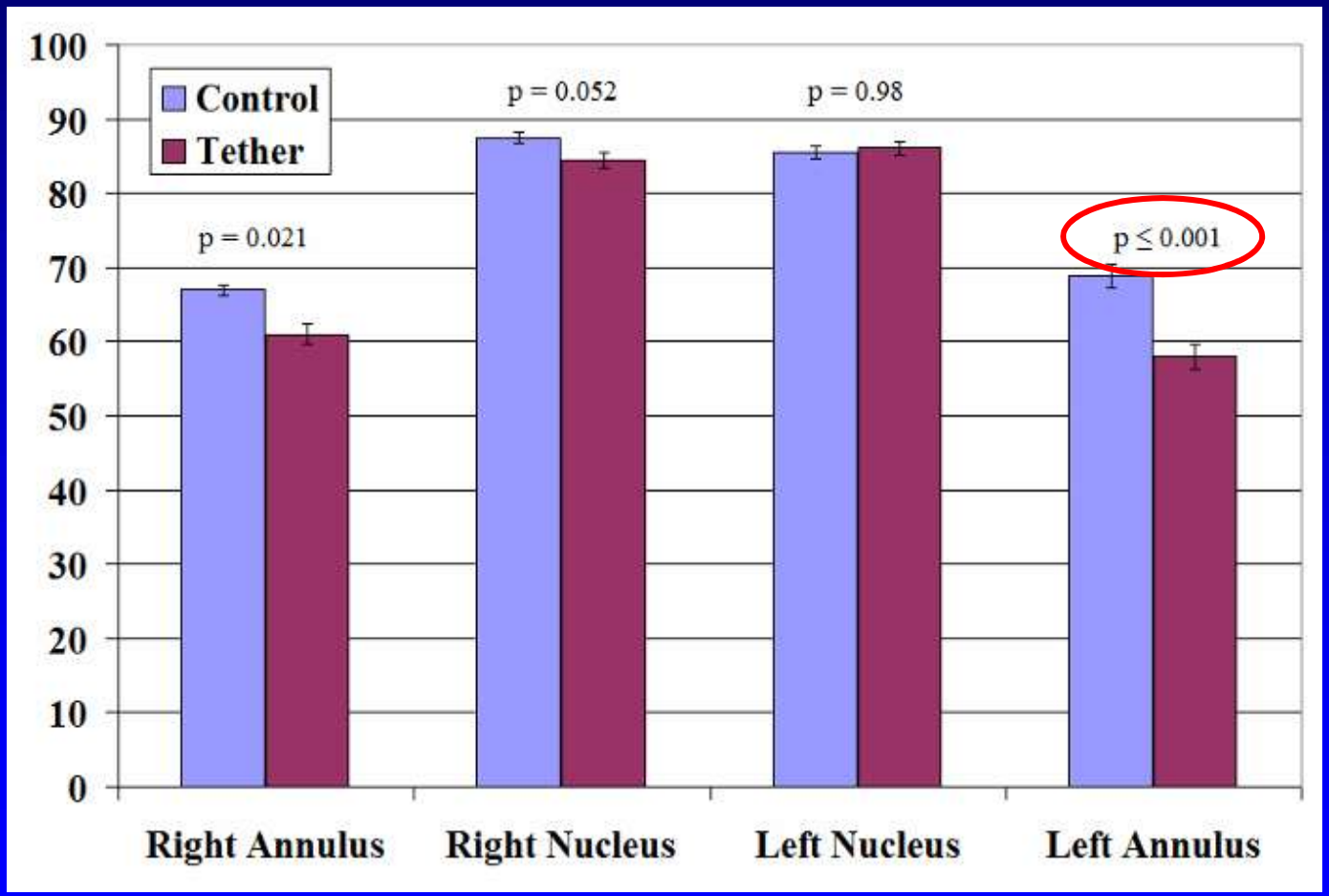
Histological grading scale based on 4 categories of degenerative changes with scores ranging from a normal disc with 4 points (1 point in each category) to a severely degenerated disc with 12 points (3 points in each category).

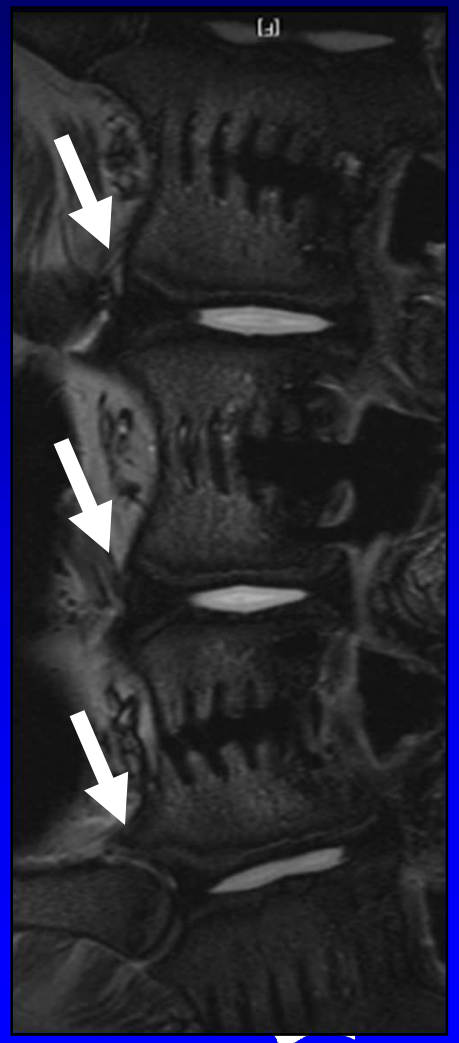
Control Discs
Average Grade:
5.27

p= 0.37

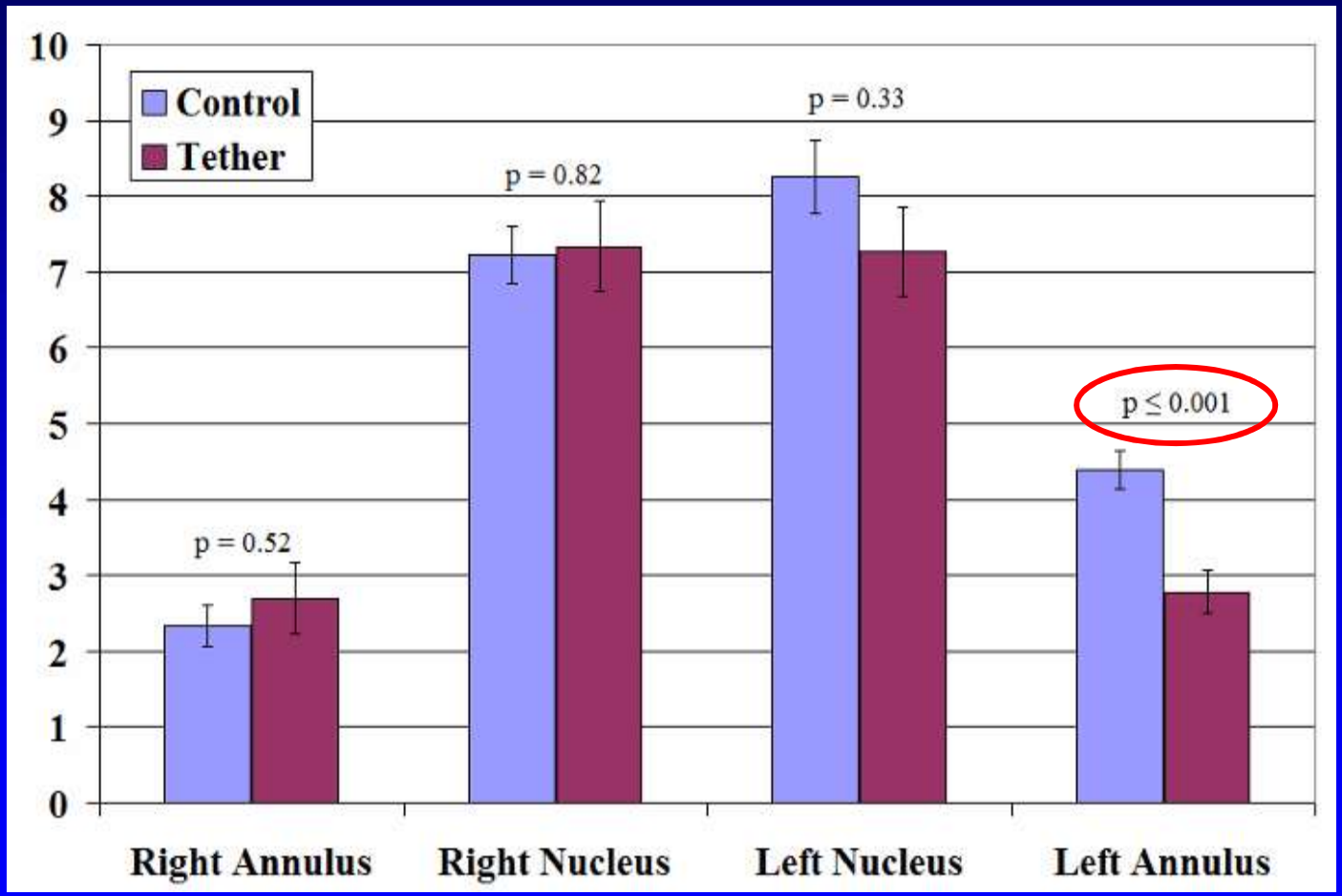
Tether Discs
Average Grade:
5.64

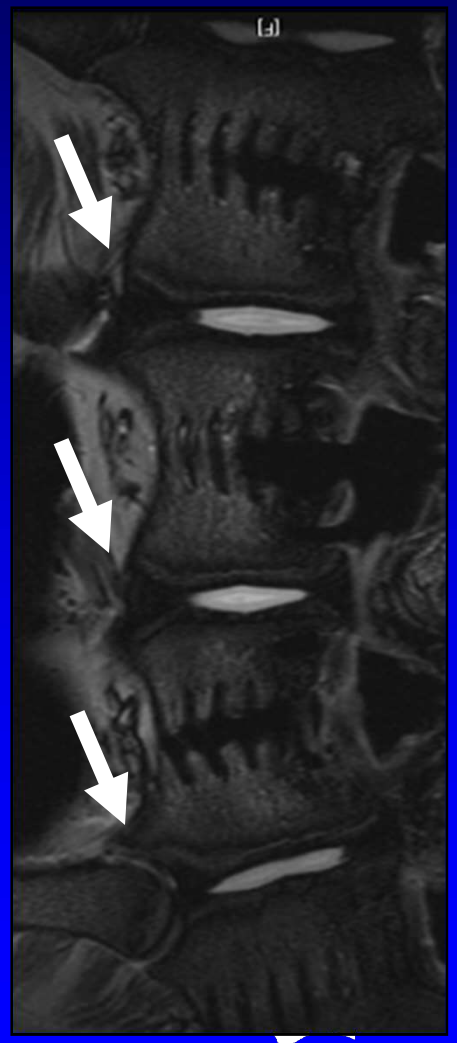
Water Content (% Wet Wt)



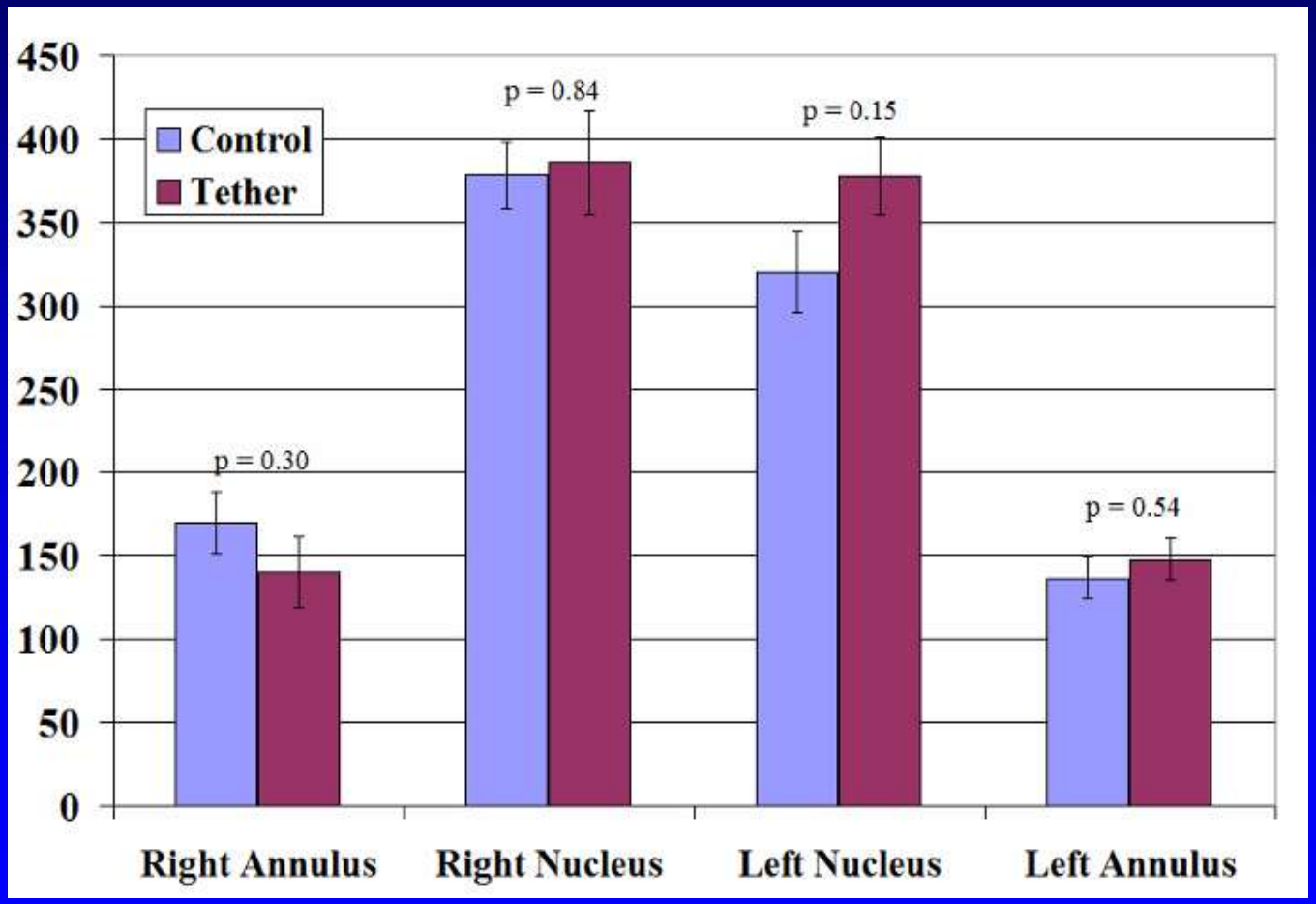


GAG Content (%WW)





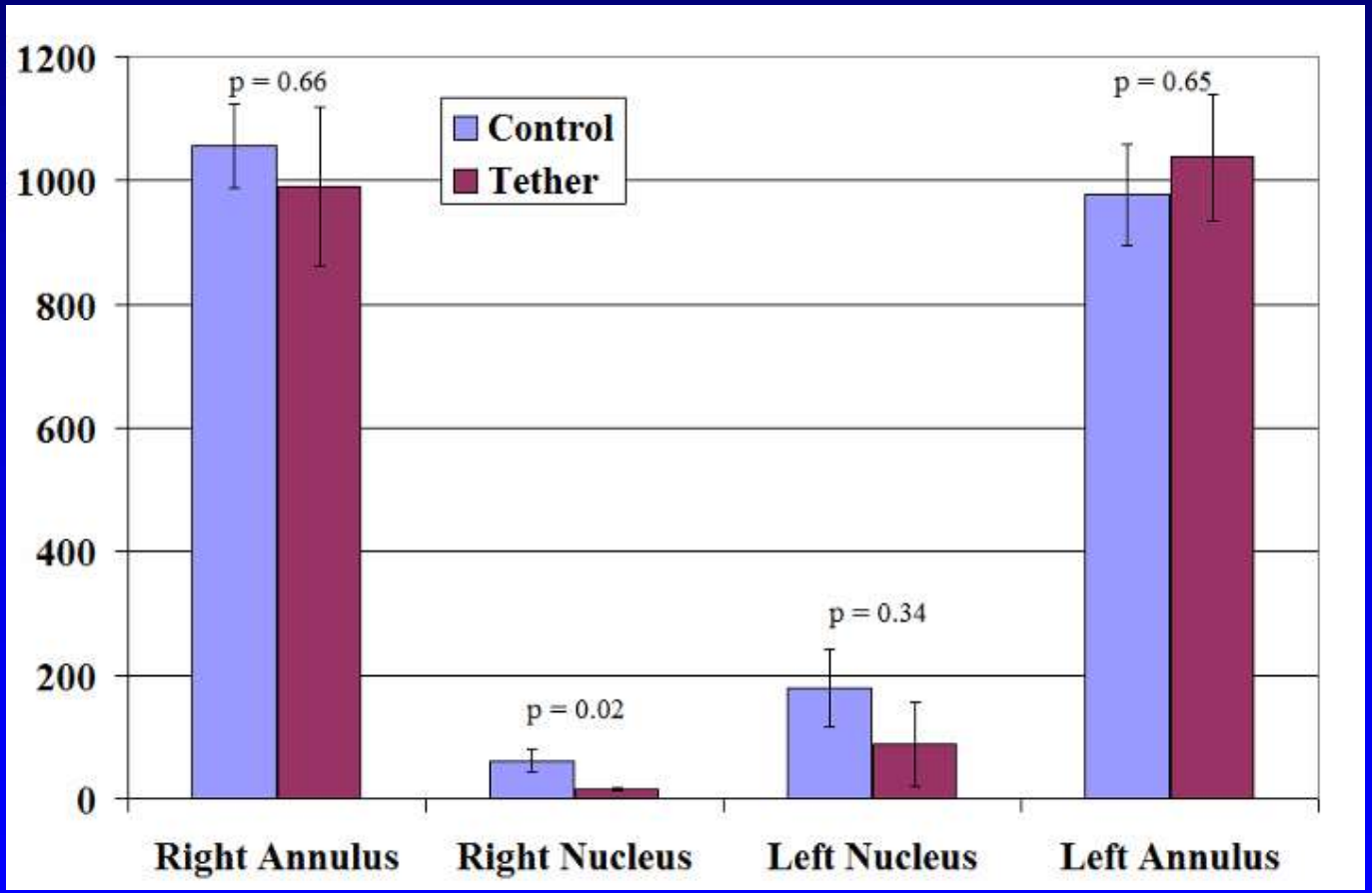
Cell Density (10^6 cells/g DW)



No significant differences between groups

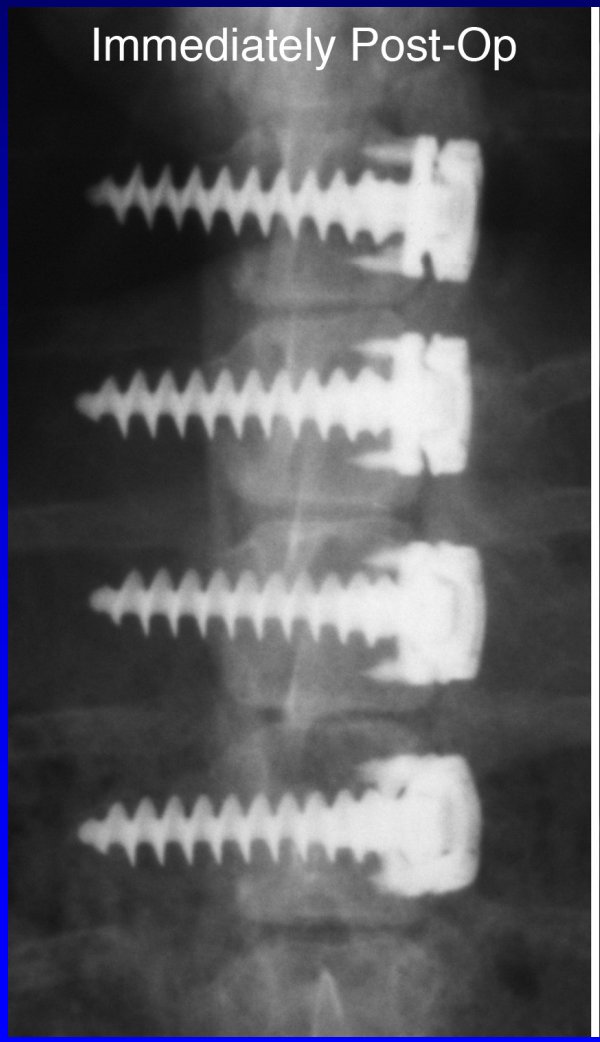
Collagen Content

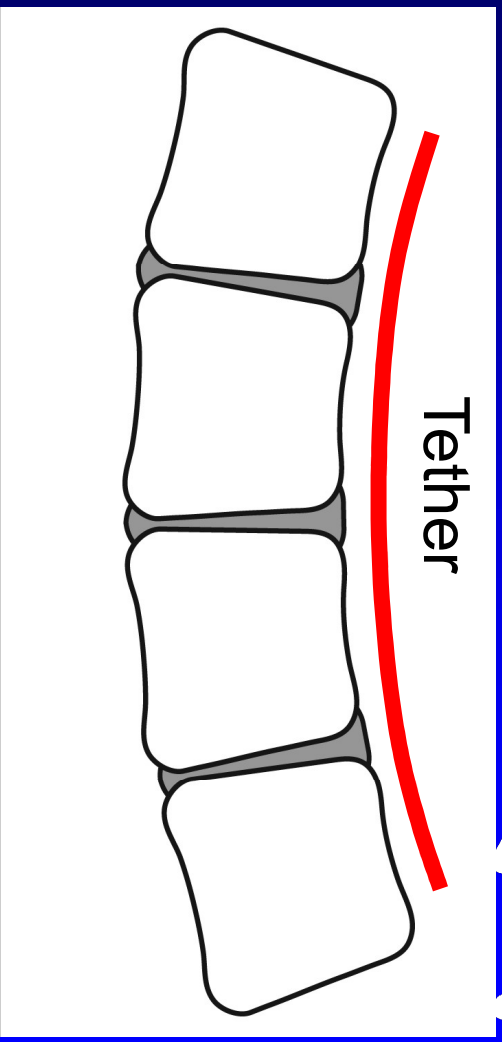
Hydroxyproline (ug/ml)



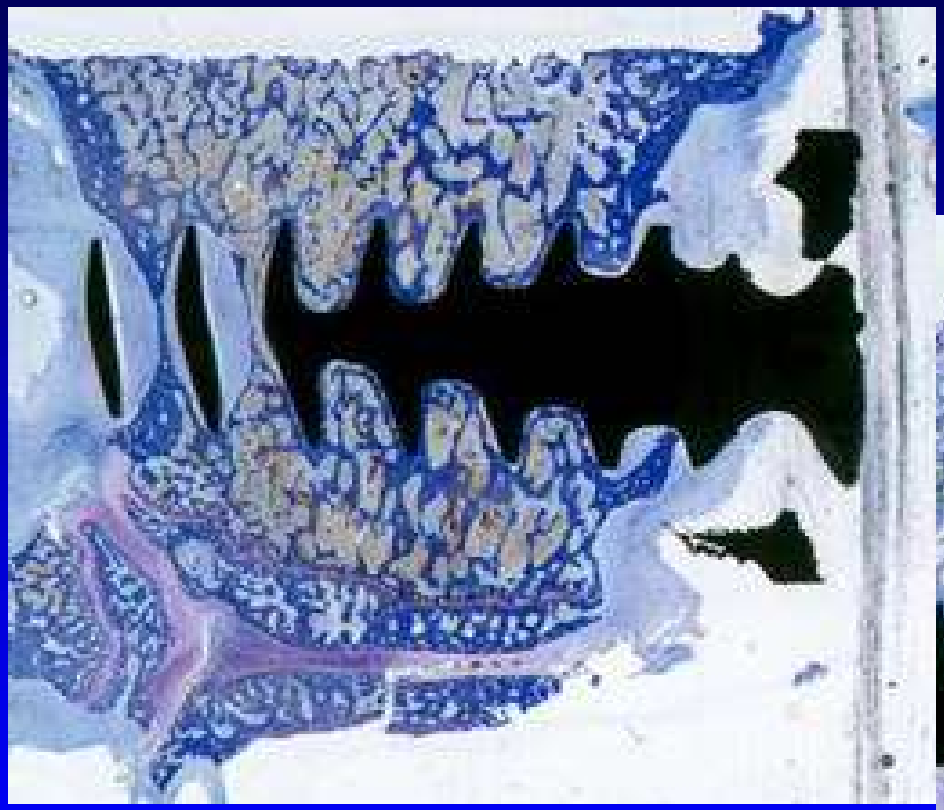
No significant differences between groups

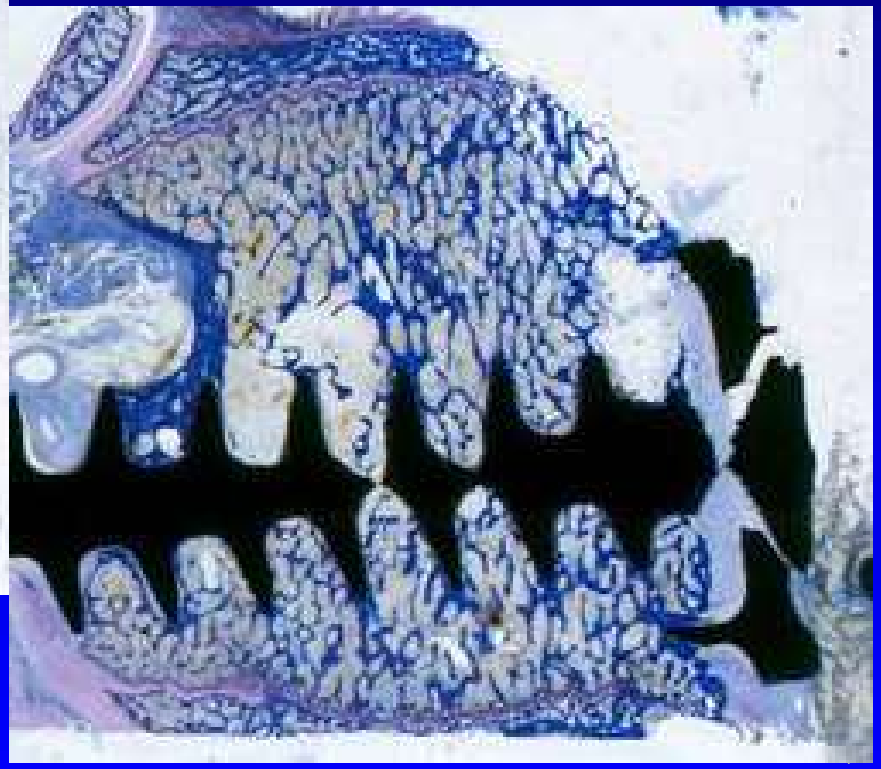
Discs wedged in the opposite direction to the vertebrae





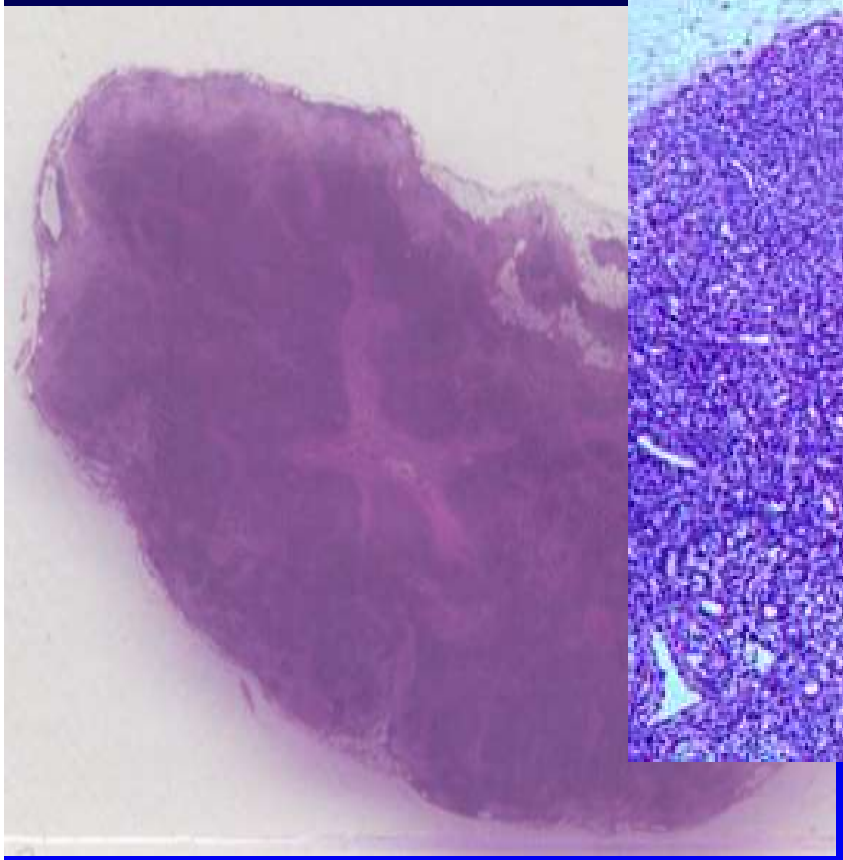
Bone-Screw Interface

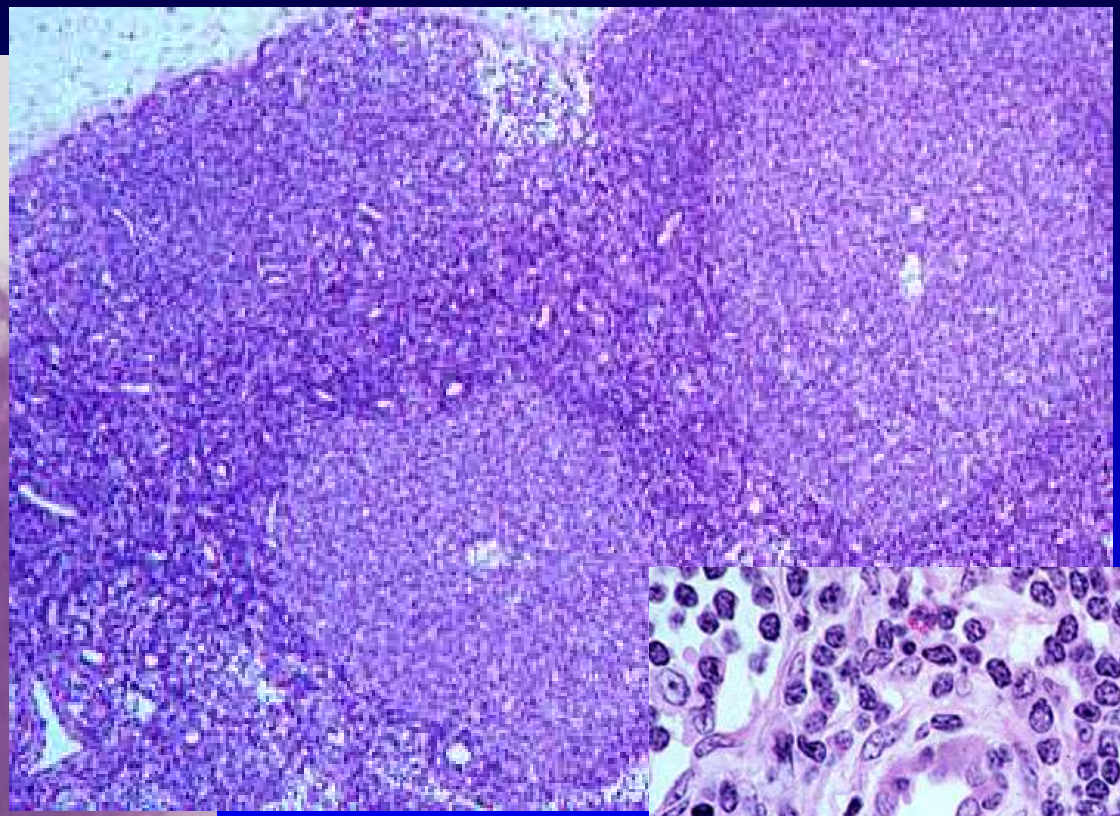


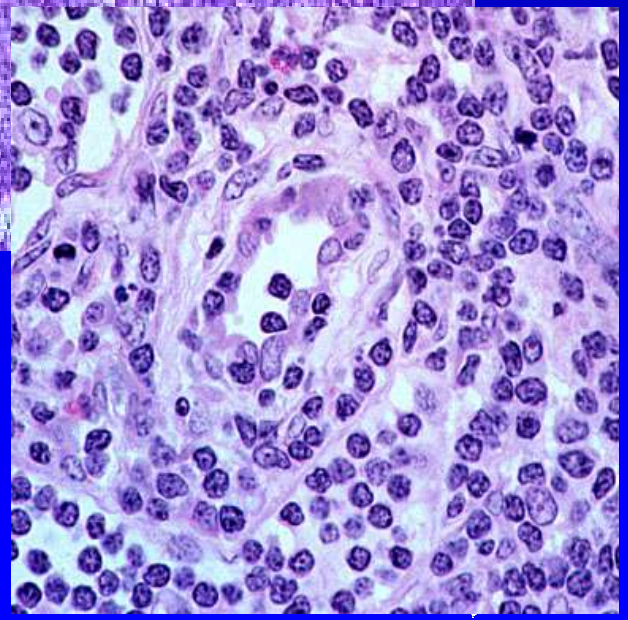


No Fibrous Zone or Loosening

Lymph Nodes



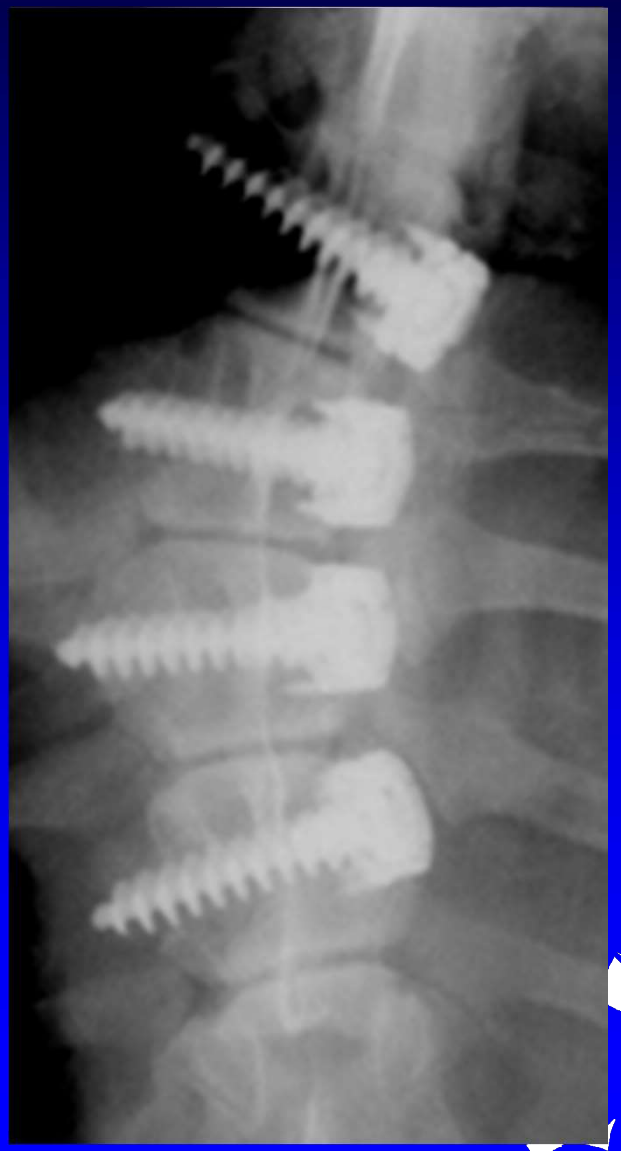




No Foreign Body Reaction

Conclusion

- **Consistent growth modulation.**
- **Disc physiology maintained.**
- **This may not be the same as correcting AIS…**

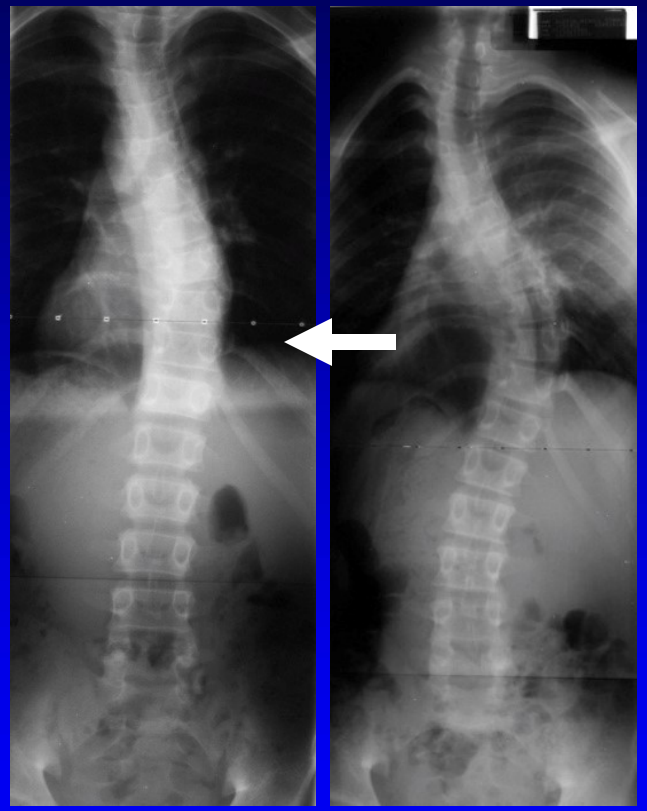


Which Method is Best?

- Staples available for off-label use, Efficacy/Indications being defined
- Plate/Staple (HemiBridge): FDA IDE pilot approved
- Tethers: Clinical trial initiated OUS

Anterior Growth Modulation

- Cautious optimism
- Potential shift in treatment
- Data supports the clinical trials



Non-Fusion Correction